NOTE

PATENTING POT: THE HAZY UNCERTAINTY SURROUNDING CANNABIS PATENTS

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INTRODUCTION

The last decade witnessed a dramatic increase in state-based legalization of recreational and medical cannabis use.[1]

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1 *See* Steve Brachmann, *U.S. Cannabis Inventions on the Rise as Legal Marijuana Market Grows*, IPWATCHDOG (Feb. 19, 2019), https://www.ipwatchdog.com/2019/02/19/us-cannabis-inventions-on-rise-legal-market-grows/id=106499/ [https://perma.cc/P8R4-6HYY].

As states changed cannabis's legality, inventors moved to establish a claim on the new marketplace by seeking intellectual property protection.[2] Correspondingly, the number of cannabis-related patents filed at the U.S. Patent and Trademark Office (PTO) increased tremendously.[3]

The rapid increase in cannabis patent applications produced patents that appear to violate 35 U.S.C §§ 102 and 103.[4] Cannabis's illegal categorization makes generating publicly disclosed materials difficult.[5] Furthermore, patent examiners lack experience in reviewing cannabis-related patents, and examiners may not notice when a patent makes claims that are too broad.[6] The fact that inventors can patent individual cannabis strains further exacerbates novelty issues because the strain may already exist in commerce (even though its composition might not be published).[7] Broad patent protection for cannabis strains and products likely creates negative long-term effects for the cannabis industry by generating a ripe market for patent litigation. Further, this harms consumers because patents increase an invention's price (in the context of medical drugs, patent protection can increase a drug's price by 400%).[8]

The rush to patent cannabis undermines patent law's goals. Patent law serves the purpose of providing a limited

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2 *See id.*

3 *See id.*

4 *See* 35 U.S.C. §§ 102, 103 (2018); *see also* U.S. Patent No. 10,413,578 (filed Aug. 10, 2017) (referencing the historical use of cannabis for its medicinal properties).

5 *See* Michael Loney, *Prior Art Shortage Could Strain US Cannabis Innovation*, MANAGING INTELL. PROP. (Jan. 23, 2019), https://www.managingip.com/Blog/3855108/Prior-art-shortage-could-strain-US-cannabis-innovation.html?ArticleId=3855108 [https://perma.cc/248J-W4N8].

6 *See* Michael Annis & Liam Reilly, *Unique Issues with Cannabis-Related Patents & Their Enforcement*, CANNABIS INDUSTRY J. (Sept. 16, 2019), https://cannabisindustryjournal.com/feature_article/unique-issues-with-cannabis-related-patents-their-enforcement/ [https://perma.cc/8L3U-3733]; *see also* ROBERT BECHER, MICHAEL T. ZELLER & BEN DACH, QUINN EMANUEL TRIAL LAWYERS, RECENT TRENDS IN CANNABIS PATENT LITIGATION (2019), https://www.quinnemanuel.com/media/1419377/recent-trends-in-cannabis-patent-litigation.pdf [perma.cc/7N64-8W63] (noting the difficulty in determining whether an invention is obvious due to the lack of prior art).

7 *See* Chris Roberts, *This Is the First Hemp Strain to Be Awarded a US Patent*, LEAFLY (Sept. 13, 2019), https://www.leafly.com/news/industry/this-is-the-first-hemp-strain-patented-in-the-us [perma.cc/S6DW-54TR] (discussing how a company received a plant patent for a popular cannabis strain which was similar to existing strains).

8 Hannah Brennan, Amy Kapczynski, Christine H. Monahan & Zain Rizvi, *A Prescription for Excessive Drug Pricing: Leveraging Government Patent Use for Health*, 18 YALE J.L. & TECH. 275, 284–85 (2016).

monopoly to compensate inventors while also increasing the public's access to knowledge—thereby serving society.[9] However, several inventors undercut this goal by filing patents that claim seemingly obvious or non-novel cannabis inventions. At least one cannabis patent explicitly recognizes that the art in this area has been well developed for thousands of years, which seemingly casts doubt on the patent's novelty.[10]

As such, cannabis patents appear to serve a more dubious purpose. Instead of pursuing patents that comport with patent law's goals, inventors are taking advantage of deregulation by filing overly broad cannabis patents at an alarming rate. This approach is reminiscent of the biotech industry's speculative approach to gene sequence patents.[11] Companies raced to patent gene sequences shortly after the announcement of the Human Genome Project.[12] However, the gene sequence patent race did not yield tremendously innovative products. Some suggest the rapid increase in patents stifled innovation by creating an "anticommons" because the high number of gene sequence patent owners increased transaction costs for researchers.[13] Some commentators posit that this race promulgated the current uncertainty surrounding § 101.[14]

The race to patent cannabis mirrors the push for receiving patent protection for gene sequences because cannabis companies are similarly focused on bolstering patent portfolios to stave off competition as opposed to patenting innovative inventions. This cart-before-the-horse approach does not comport with patent law's goals. Furthermore, the approach prevents consumers from receiving the fruits of a competitive and innovative marketplace.

This Note explains the problems that surround cannabis patents. Part I provides an overview of patent law and discusses cannabis's regulatory history. Part II expands on the topics discussed in Part I and explains how the lack of prior art

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9 Grant v. Raymond, 31 U.S. 218, 243 (1832).

10 *See* U.S. Patent No. 10,413,578 (filed Aug. 10, 2017) (stating "[c]annabis use for medicinal purposes dates back at least 3,000 years").

11 *See* Wesley M. Cohen, *Patents and Appropriation: Concerns and Evidence*, 30 J. TECH. TRANSFER 57, 61 (2005).

12 *See* Robert Cook-Deegan & Christopher Heaney, *Patents in Genomics and Human Genetics*, 11 ANN. REV. GENOMICS & HUM. GENETICS 383, 384 fig.1, 400 (2010).

13 *See id.* at 407; *see also* Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 SCIENCE 698, 698 (1998) ("[P]rivatization can go astray when too many owners hold rights in previous discoveries that constitute obstacles to future research.")

14 *See* Cook-Deegan & Heaney, *supra* note 12, at 407–10, 415.

within the cannabis space promulgates uncertainty for cannabis inventors. Part III argues for stronger claim requirements in cannabis patents and advocates for greater flexibility when factfinders evaluate cannabis patents. Further, Part III suggests alternative approaches to claim construction for challenged cannabis patents.

I
PATENT LAW BACKGROUND AND THE REGULATORY HISTORY BEHIND CANNABIS

One cannot fully understand the issues surrounding cannabis patents without knowing patent law's basic foundations. Part I first provides some background information on patent law. Then it introduces how cannabis fits—or fails to fit—within patent law's general framework by discussing cannabis's regulatory history.

Title 35 of the United States Code establishes the patent system's framework.[15] However, the Comprehensive Drug Abuse Prevention and Control Act of 1970 (CSA) complicates how cannabis fits into this framework.[16] The CSA created a gap between the legally sufficient standard and the practical standard for patenting cannabis because the CSA designated cannabis as a Schedule I substance.[17] This discouraged cannabis research and deprived cannabis inventors of traditional forms of prior art references.[18] Further, the CSA created doubt among commentators as to whether Schedule I substances meet § 101's utility requirement.[19]

A. Patent Law's General Framework

Patent law's constitutional protections are codified and expanded upon under Title 35 of the United States Code. The Code provides requirements for obtaining a patent[20] and estab-

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15 *See generally* 35 U.S.C. §§ 1–390 (2018) (creating PTO and enumerating its powers and duties).

16 *See* Comprehensive Drug Abuse Prevention and Control Act of 1970, Pub. L. No. 91-513, § 202, 84 Stat. 1236, 1248–49 (codified at 21 U.S.C. § 812(c) (2018)) (criminalizing the possession, use, and distribution of cannabis).

17 *Id.*

18 *See* NAT'L ACADS. OF SCIS., ENG'G, & MED., THE HEALTH EFFECTS OF CANNABIS AND CANNABINOIDS: THE CURRENT STATE OF EVIDENCE AND RECOMMENDATIONS FOR RESEARCH 382–84 (2017) (explaining the difficulty in accessing the cannabis product "necessary to address specific research questions").

19 *See* William J. McNichol, Jr., *The New Highwayman: Enforcement of U.S. Patents on Cannabis Products*, 101 J. PAT. & TRADEMARK OFF. SOC'Y 24, 39–40 (2019).

20 35 U.S.C. §§ 101–03 (2018).

lishes the PTO as the administrative agency that reviews patent applications.[21]

The PTO reviews applications for three types of patents: design patents, plant patents, and utility patents.[22] The PTO grants design patents to inventors "who create[ ] a new, original, and ornamental design for an article of manufacture."[23] Persons who invent or discover and reproduce a new plant may obtain a plant patent.[24] Utility patents are the most common patents, and utility patents cover "machine[s], vital process[es], composition[s] of matter, article[s] of manufacture, or any useful improvement thereof."[25]

The type of patent determines the invention's protection of market exclusivity term by providing the invention patent protection for a stated number of years. Plant patents receive patent protection for fourteen years from the patents' filing date, whereas utility patents receive patent protection for twenty years after the filing date if the inventor filed the patent after June 8, 1995.[26] Inventors may extend utility patents, which is especially prevalent among biotech and pharmaceutical companies seeking to recoup lost time from research, development, and the time required to receive regulatory approval.[27]

Patents must meet Title 35's requirements to receive patent approval from the PTO. The requirements include eligible subject matter (§ 101), utility (§ 101), novelty (§ 102), nonobviousness (§ 103), and enablement (§ 112).[28] The requirements set the floor for patentability. Furthermore, Title 35 provides requirements for plant patents under Section 161.[29] Section 161's requirements incorporate the requirements set forth under §§ 101, 102, 103, and 112.[30] Notably, the Supreme Court upheld broad patent protection in *Diamond v. Chakrabarty* by allowing for "unforeseeable" inventions to receive patent protection.[31] The Court allowed the PTO to grant patents for living things—such as genetically modified orga-

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21 *Id.* § 1.

22 JOANNA T. BROUGHER, INTELLECTUAL PROPERTY AND HEALTH TECHNOLOGIES: BALANCING INNOVATION AND THE PUBLIC'S HEALTH 6–7 (2014).

23 *Id.* at 7.

24 *Id.*

25 *Id.* at 6.

26 *Id.* at 116 (discussing the change in patent protection term as a result of Congress adopting the date-of-filing standard).

27 *Id.* at 116–18

28 *Id.* at 7–8 (citing 35 U.S.C. §§ 101–03, 112 (2018)).

29 35 U.S.C. § 161.

30 *Id.*

31 447 U.S. 303, 316 (1980).

nisms—and in doing so, the Court declined to answer the question of whether patents must pass a morality standard.[32]

1. *Section 101 and Patentable Subject Matter*

The Supreme Court created a new approach for § 101 inquiries over the last decade. Prior to the recently decided Supreme Court cases, many regarded § 101 as a low barrier to obtaining patent protection.[33] The Court's decisions, and subsequent PTO guidance, however, complicates the standard for patentability under §-101.

In 2010, the Supreme Court evaluated the subject matter eligibility of a process patent under § 101 in *Bilski v. Kappos*.[34] There, the Court held that the machine-or-transformation test is not dispositive for determining whether a process is patentable under § 101.[35] Rather, the Court denied the patent application because the patent sought to protect an abstract idea, which falls out of § 101's scope.[36] Thus, while the Court expanded the inquiry into what constitutes a patentable subject matter, *Bilski* actually relaxed the standard.[37]

The Court revisited § 101 in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.* Prometheus sued Mayo for infringing on Prometheus's patented metabolite tests, and the Federal Circuit held in favor of Prometheus under the machine-or-transformation test.[38] On review, the Supreme Court invalidated Prometheus's patents under § 101 because the patents covered "conventional activity already engaged in by the scientific community."[39] The Court's decision narrowed § 101's scope by removing inventions that expound on scientific principles from eligible subject matter.[40]

The Court later expanded its strict subject matter requirements to patents outside of the pharmaceutical space. In *Alice Corp. v. CLS Bank International*, the Court evaluated whether a

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32 *See id*; *see also* Juicy Whip, Inc. v. Orange Bang, Inc., 185 F.3d 1364, 1367 (Fed. Cir. 1999) (holding the utility requirement did not preclude a patent application for a deceptive invention); BROUGHER, *supra* note 22, at 53–54 (discussing the Supreme Court's decision in *Diamond v. Chakrabarty*).

33 *See* JOHN I. GALLIN & FREDERICK P. OGNIBENE, PRINCIPLES AND PRACTICE OF CLINICAL RESEARCH 320 (3d ed. 2012).

34 Bilski v. Kappos, 561 U.S. 593, 598 (2010).

35 *Id.* at 604.

36 *Id.* at 611–12.

37 *See* BROUGHER, *supra* note 22, at 16.

38 *See id.* at 81.

39 *Id.* at 82 (quoting Mayo Collaborative Servs. v. Prometheus Labs., Inc., 566 U.S. 66, 80 (2012)).

40 *See id.*

company's patent, which claimed a method for measuring financial risk, violated § 101.[41] The Court determined the patent claimed an ineligible subject matter because the patent directed its claims at an "abstract idea."[42] The Court—relying on *Mayo*—proceeded to formulate a test for subject matter eligibility under § 101.[43] These decisions form the current "threshold test" for what satisfies an eligible subject matter under § 101.[44]

2. *Sections 102 and 103—Novelty and Nonobviousness*

Section 102 provides patent protection for new inventions that were not previously available to the public.[45] Section 103 also prohibits obvious inventions from receiving patent protection.[46] Therefore, inventors cannot patent derivative works. Section 103 excludes inventions if the invention would be obvious to a person reasonably skilled in the art.[47] The levels of novelty and nonobviousness are difficult to determine, and parties often challenge a patent's validity under these sections. Notably, plant patents incorporate §§ 102 and 103's requirements under § 161 reference to "provisions of this title."[48]

Sections 102 and 103 implicate prior art—an important part of patent law. The PTO gives due regard to the pertinent art during the patent prosecution stage by taking a broad approach towards claim construction.[49] PTO examiners deny patent applications that violate the examiners' broad interpretation of the pertinent art.[50] The PTO imposes this broad standard because inventors may "amend [their] claims to obtain protection commensurate with [their] actual contribution to the

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41 Alice Corp. v. CLS Bank Int'l, 573 U.S. 208, 212 (2014).

42 *Id.*

43 *Id.* at 217. The Court stated that the proper inquiry is to first establish "whether the claims at issue are directed to one of those patent-ineligible concepts . . . then ask, what else is there in the claims before us?" *Id.* (internal quotation marks omitted).

44 *See* Blaine H. Evanson & Matthew W. Samuels, *The True Threshold of Patent Eligibility*, L.A. DAILY J. (Aug. 15, 2014), https://www.gibsondunn.com/wp-content/uploads/documents/publications/EvansonSamuels-TrueThresholdOfPatentEligibility-Aug2014.pdf [https://perma.cc/XK4T-G2HF].

45 35 U.S.C. § 102 (2018); *see also* BROUGHER, *supra* note 22, at 22 (discussing the novelty requirements in § 102).

46 35 U.S.C. § 103.

47 *See* BROUGHER, *supra* note 22, at 22.

48 35 U.S.C. § 161; *see also, e.g.*, *In re* LeGrice, 301 F.2d 929, 931 (C.C.P.A 1962) (discussing § 161's incorporation of other requirements included under Title 35).

49 *See In re* Yamamoto, 740 F.2d 1569, 1571 (Fed. Cir. 1984).

50 *See id.*

art."[51] Furthermore, construing claims broadly "serves the public interest by reducing the possibility that claims, finally allowed, will be given broader scope than is justified."[52]

Prior art is generally defined under § 102(a) and includes any disclosure made publicly available.[53] Notably, when Congress passed the American Invents Act (AIA) it eliminated the room for interpretation that § 102 applied to private offers for sale, private uses, and secret processes; rather, the AIA stipulated that § 102 only applies to inventions that have been made *openly available* to the public.[54] Thus, the new standard does not exclude inventions from obtaining patent protection if the invention was previously used in secret.[55]

The prior art inquiry shifts—albeit moderately—under § 103. Under § 103, an invention cannot receive patent protection if the differences between the invention's claimed subject matter and "the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains."[56] However, determining obviousness under § 103 recently shifted from evaluating obviousness from the date of invention to evaluating obviousness at the date of filing the patent.[57]

Prior art challenges vary in substance and in form. Firstly, the AIA grants third parties an opportunity to invalidate a patent at the application stage.[58] The AIA allows third parties to submit prior art findings directly to the Patent Trial and Appeal Board (PTAB) for a re-examination under an *inter partes* review

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51 *Id.* (quoting *In re* Prater, 415 F.2d 1393, 1404–05 (C.C.P.A. 1969)).

52 *Id.*

53 35 U.S.C. § 102(a); *see also* 1 ERIC E. BENSEN, PATENT LAW PERSPECTIVES § 2A.2[1] (2019) (explaining sources of prior art). Additionally, courts have incorporated § 102's meaning of prior art to apply to the use of the term in § 103. *See, e.g.*, *In re* Fout, 675 F.2d 297, 300 n.3 (C.C.P.A. 1982) (explaining that material may be "prior art" within the meaning of § 103 although that material is not mentioned in § 102).

54 *See* Joe Matal, *A Guide to the Legislative History of the America Invents Act: Part I of II*, 21 FED. CIR. B.J. 435, 467 (2012).

55 *See* BENSEN, *supra* note 53, at § 2A.2[2]. *But see* Helsinn Healthcare S.A. v. Teva Pharm. USA, Inc., 139 S. Ct. 628, 629 (2019) (holding that a commercial sale to a third party who is required to keep the invention confidential may place the invention "on sale" under the AIA).

56 KSR Int'l Co. v. Teleflex Inc., 550 U.S. 398, 406 (2007) (internal quotation marks omitted).

57 *See* BENSEN, *supra* note 53, at § 2B.1.

58 *See* Leahy-Smith America Invents Act, Pub. L. No. 112-29, § 8, 125 Stat. 284, 316 (2011).

(IPR).[59] Third parties must do so within six months of the patent's publication.[60] Petitioners must submit prior art and show some "reasonable likelihood that the petitioner would prevail with respect to at least one challenged claim" to bring forth an IPR.[61] The PTAB interprets the patents under the "broadest reasonable interpretation."[62] The ability to challenge a patent's validity at the PTAB is not extinguished at six months.[63] Third parties may bring forth a post-grant review (PGR) within nine months of patent approval or file an IPR with the PTO nine months after the PTO grants the patent.[64]

B. Cannabis's Regulatory Scheme

Cannabis's complicated history does not produce a seamless mold for integrating cannabis into patent law's requirements. Due to cannabis's history, unclarity exists when patenting "new" cannabis uses. Federal treatment of cannabis over the last fifty years provides a useful starting point for understanding the problems looming within the PTO's stack of cannabis patent applications.[65]

The United States tightened cannabis regulations under the CSA. The CSA classified "marihuana" and tetrahydrocannabinol (THC) as Schedule I drugs and imposed felony charges

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59 *See id.* at 299; *see also* BROUGHER, *supra* note 22, at 17 (noting that the AIA permits third parties to submit prior art findings). Additionally, the Hatch-Waxman Act provides generic drug companies an incentive to challenge patents by granting successful patent challengers short-term generic market exclusivity. The generic company can file an abbreviated new drug application and include undisclosed prior art to invalidate the patent. *See* Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, § 101, 98 Stat. 1585, 1585.

60 *See* Leahy-Smith America Invents Act § 8.

61 BROUGHER, *supra* note 22, at 18.

62 *See* Trivascular, Inc. v. Samuels, 812 F.3d 1056, 1062 (Fed. Cir. 2016).

63 *See* Leahy-Smith America Invents Act § 8.

64 *See id.* § 6; *see also* BROUGHER, *supra* note 22, at 17–18 (noting the time frame for filing a petition for PGR review). The AIA also established another form for invalidating patents using prior art for covered business methods; however, the AIA requires that the person bringing the IPR must be a "person or the person's real party in interest or privy [who] has been sued for infringement of the patent." Leahy-Smith America Invents Act § 18. The Federal Circuit, however, held that these patents must be "financial in nature." Secure Axcess, L.L.C. v. PNC Bank Nat'l Ass'n, 848 F.3d 1370, 1381 (Fed. Cir. 2017), *vacated*, 138 S. Ct. 1982 (2018).

65 Matthew Bultman, *Cannabis Patent Activity Surges Amid Industry Gold Rush*, LAW360 (Oct. 16, 2019, 5:25 PM) https://www.law360.com/articles/1203746/cannabis-patent-activity-surges-amid-industry-gold-rush [https://perma.cc/GG37-K4JV] (stating "the USPTO received nearly 550 cannabis-related applications . . . on par with filing activity for the entire period from 2010 to 2016").

for cannabis possession.[66] This designation remains in place to date. However, states began to carve out exceptions to federal prohibition via compassionate use legislation in 1996.[67]

Cannabis's designation as a Schedule I drug makes medical research particularly difficult. Three different federal agencies—the Drug Enforcement Agency (DEA), the Food and Drug Administration (FDA), and the National Institute on Drug Abuse (NIDA)—must approve cannabis research projects.[68] Due to marijuana's illicit characterization, cannabis researchers must use NIDA to supply cannabis. However, NIDA tends to provide cannabis to researchers that are focused on curbing substance abuse rather than providing equal access to researchers studying cannabis's potential health benefits.[69] Additionally, NIDA uses the University of Mississippi as its sole cannabis supplier, which further impacts researchers' access to cannabis.[70] Furthermore, some state boards impose additional requirements on researchers. These state boards often require researchers to obtain a "controlled substance certificate" from a board of medical examiners to conduct research involving cannabis.[71]

Recent changes to the law provide greater latitude within the cannabis space. In 2018, Congress passed the Agriculture Improvement Act of 2018 (Farm Bill), which lifted regulations against growing hemp and conducting hemp-related research.[72] This could provide the cannabis industry with greater access to resources. However, the Farm Bill defined hemp narrowly and required growers to ensure that plants maintain a THC profile of less than .3%.[73] Thus, the Farm Bill will not likely produce an immediate increase in the volume of cannabis research, leaving the industry without an avenue to develop robust sources of prior art.

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66 *See* Comprehensive Drug Abuse Prevention and Control Act of 1970, Pub. L. No. 91-513, § 401, 84 Stat. 1236, 1261 (codified at 21 U.S.C. § 812(c)(10), (17) (2018)).

67 Compassionate Use Act of 1996, CAL. HEALTH & SAFETY CODE § 11362.5. Under compassionate use legislation, states permit clinically ill patients to use cannabis products to treat the patients' condition. *Id.*

68 *FDA and Cannabis: Research and Drug Approval Process*, U.S. FOOD & DRUG ADMIN. (Oct. 10, 2020), https://www.fda.gov/news-events/public-health-focus/marijuana-research-human-subjects [https://perma.cc/EH2X-P3FR].

69 NAT'L ACADS. OF SCIS., ENG'G, & MED., *supra* note 18, at 382.

70 *Id.* at 382 & n.18.

71 *Id.* at 380.

72 Agricultural Improvement Act of 2018, Pub. L. No. 115-334, § 7129, 132 Stat. 4490, 4495.

73 *Id.* [continue here]

II
PROBLEMS WITH CANNABIS PATENTS

Cannabis's complicated history creates opportunities for speculative inventors that seek greater exclusivity over the cannabis market. Practitioners and commentators recognize that, as a general practice, drafting claims broadly grants wider patent protection.[74] However, cannabis patent drafters should not adopt this practice due to lack of prior art in the space. Cannabis's complicated regulatory history promulgates unclarity around the prior art framework—attributable to the lack of research and the examiners' lack of industry-specific knowledge.[75] This unclarity creates negative downstream effects, which increase litigation regarding patent infringement and patent enforcement actions. Due to limitations in prior art, examiners may grant patent protection to claims with "hidden problems such as lack of novelty, obviousness, and inherent anticipation."[76] This adversely impacts inventors in the cannabis space because the inventors lack certainty regarding their patents' validity and could raise the prices for consumers.

A. Cannabis and § 101—Is the Subject Matter Patentable?

The PTO first granted a cannabis patent in the 1940s.[77] However, the CSA failed to specify whether Schedule I substances could meet § 101's threshold, which creates some ambiguity around cannabis's eligibility under § 101. Some argue that illegal substances lack utility and therefore fall outside of § 101's scope. However, drugs that contain a Schedule I substance must receive approval from the FDA and be rescheduled

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74 *See* Donald Chisum, *Critique*: *Weak Points in Basic Framework of Mayo*, CHISUM PAT. L. REFERENCE GUIDES (2012), https://www.chisum.com/cplrg-guides/0079 [https://perma.cc/CT3B-WHZM]; *see also* JOANNA BROUGHER, BILLION DOLLAR PATENTS: STRATEGIES FOR FINDING OPPORTUNITIES, GENERATING VALUE, AND PROTECTING YOUR INVENTIONS loc. 578–90 (ebook) (discussing the broad patent claims granted to BioTech's 9,095,554 cannabis related patent). By granting BioTech broad claims with respect to cannabis plant composition, the PTO left a confusing framework for future cannabis-related patent prosecutions. *Id. But see generally id.* at 516–41 (discussing the adverse fiscal impacts created by non-specific patent claims).

75 *See* Annis & Reilly, *supra* note 6.

76 BROUGHER, *supra* note 74, at 592; *accord* Ben Adlin, *Did a Cannabis Company Just Patent the Spliff?*, LEAFLY (Apr. 25, 2019), https://www.leafly.com/news/industry/did-corporate-cannabis-just-patent-the-spliff [https://perma.cc/CV2B-8JSG] (discussing Vireo Health's patent, U.S. Patent No. 10369178, for "tobacco products infused with cannabis").

77 *See* U.S. Pat. No. 2,304,669 (issued Dec. 8, 1942).

by the DEA before entering the market.[78] When the DEA and FDA vet the drug's legality and efficacy, the PTO should defer to the Agencies and approve the patent, so long as the patent meets Title 35's other requirements.[79] Thus, as a practical matter, approved drugs that contain cannabis likely comport with § 101's utility requirement. However, cannabis's utility blurs with respect to its recreational use.

Caselaw seemingly dictates that the United States does not require patents to cover a legal or moral invention.[80] However, some commentators believe that the PTO's authority to grant cannabis patents is limited to the medical setting, and that recreational cannabis patents lack the utility required under § 101.[81] These commentators believe that the common law doctrine, *ex turpi causa non oritur actio* (hereinafter the "Illegality Rule"), excludes inventions that contain per se illegal substances from obtaining patent protection.[82] Others suggest that cannabis patents are invalid under § 101 when the patents target naturally occurring compounds.[83]

These views seem untenable, and they likely violate the Supreme Court's recent § 101 precedent. The United States Constitution serves as the basis for both patent and trademark law.[84] Congress subsequently codified patent requirements under Title 35 of the U.S. Code[85] and trademark requirements under Title 37 of the Code of Federal Regulations.[86] Title 37

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78 *See* McNichol, *supra* note 19, at 29–32; *see also* Christopher Wilkins, *Is It Possible To Enforce A Cannabis Patent?*, MONDAQ (Nov. 21, 2019), http://www.mondaq.com/uk/x/866178/food†rugs+law/Is+It+Possible+To+Enforce+A+Cannabis+Patent [https://perma.cc/VEK3-3ZLX] (discussing how the Illegality Rule might bar cannabis patents in the U.K.).

79 *See* McNichol, *supra* note 19, at 39.

80 Juicy Whip, Inc. v. Orange Bang, Inc., 185 F.3d, 1364, 1366–67 (Fed. Cir. 1999), *vacated*, 382 F.3d 1367 (Fed. Cir. 2004); *see also* Fuller v. Berger, 120 F. 274, 274 (7th Cir. 1903) (asserting that the utility of an invention is not "void for lack of utility" simply because it can be used for "immoral" or illicit purposes); ALBERT H. WALKER, TEXT-BOOK OF THE PATENT LAWS OF THE UNITED STATES OF AMERICA § 82, at 54–55 (1883) ("An important question relevant to utility in this aspect, may hereafter arise and call for judicial decision. . . . [I]s utility negatived by the mere fact that the thing in question is sometimes injurious to morals, or to health, or to good order? Th[is] . . . hypothesis cannot stand, because if it could, it would be fatal to patents for steam-engines, telegraphs, electric lights, and indeed many of the noblest inventions of the nineteenth century.").

81 *See* McNichol, *supra* note 19, at 40.

82 *Id.*

83 *See* United Cannabis Corp. v. Pure Hemp Collective Inc., No. 18-cv-1922-WJM-NYW, 2019 U.S. Dist. LEXIS 66092, at *4–5, *15 (D. Colo. Apr. 17, 2019).

84 *See* U.S. CONST. art. I, § 8, cl. 8.

85 Act of July 19, 1952, Pub. L. No. 82-593, 66 Stat. 792 (1952) (codified as amended at 35 U.S.C. § 1 (2018)).

86 *See* 37 C.F.R. § 2.1 (2020).

contains a section on compliance with other laws, which Title 35 does not include.[87] Section 2.69 of Title 37 dictates that the PTO may inquire as to the trademark's "lawfulness."[88] Courts interpret this Section as applying to lawful use at the *federal* level.[89]

Patent law, however, has no such lawful use requirement. Instead, courts apply § 101 broadly to "include anything under the sun that is made by man."[90] Part I of this Note outlined the Court's recent retreat from § 101's broad understanding, but these decisions do appear to create a per se bar against cannabis patents. Supporters of the Illegality Rule appear to ignore the Court's § 101 decisions. In *Chakrabarty,* the Court evaluated the legislative history behind the Patent Act of 1793 and determined that inventions that rise above a simple manifestation of nature satisfy § 101.[91] The Court's analysis in *Chakrabarty* and its subsequent § 101 precedent likely prove fatal to the Illegality Rule.

Furthermore, general canons of statutory interpretation likely support efforts to patent cannabis. Firstly, Congress did not place an analogous section in Title 35 to Title 37's lawful use section. Thus, the Illegality Rule would force courts to read in a lawfulness requirement to Title 35 despite Congress declining to include the requirement. This violates the Court's use of *expressio unius*, a well-settled canon of statutory interpretation.[92] While *expressio unius* generally applies to terms within the same statute, some courts have applied the canon to powers enumerated in the Constitution.[93] In keeping with this canon of statutory interpretation, courts could look to other areas of the Code that expressly prohibit specific types of pat-

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87 *See* 37 C.F.R. § 2.69.

88 *Id.*

89 *See In re* Brown, 119 U.S.P.Q.2d 1350, 1351 (T.T.A.B. 2016) ("[T]he fact that the provision of a product or service may be lawful within a state?is irrelevant to the question of federal registration when it is unlawful under federal law." (internal citations omitted)); *cf.* U.S. PATENT AND TRADEMARK OFFICE, EXAMINATION OF MARKS FOR CANNABIS AND CANNABIS-RELATED GOODS AND SERVICES AFTER ENACTMENT OF THE 2018 FARM BILL 3 (2019), https://www.uspto.gov/sites/default/files/documents/Exam%20Guide%201-19.pdf [https://perma.cc/XF6L-HXXN] (stating that hemp trademarks must comply with the CSA and the Farm Bill.).

90 Diamond v. Chakrabarty, 447 U.S. 303, 309 n.6 (1980) (internal quotation marks omitted).

91 *See id.* at 308–09.

92 *See, e.g.*, Hamdan v. Rumsfeld, 548 U.S. 557, 578 (2006) (stating "a negative inference may be drawn from the exclusion of language from one statutory provision that is included in other provisions of the same statute").

93 *See, e.g.*, Powell v. McCormack, 395 F.2d 577, 587–88 (D.C. Cir. 1968) (applying *expressio unius* to constitutional interpretation).

ents. Under Title 42, inventors may not patent inventions that cover atomic energy or nuclear weapons.[94] Thus, Congress clearly contemplated some instances that necessitate a carve-out from patentability under § 101. Given these statutory inconsistencies, the Illegality Rule should not apply to cannabis patents.

The second approach lacks precedential basis and is too generic. Barring patent protection for cannabis merely because the patent contains claims to naturally occurring compounds ignores the inventive step involved in synthesizing cannabinoids.[95] While inventors may currently benefit from the dearth of documentary evidence in the cannabis space, a per se bar to subject matter eligibility would inappropriately deter research. Researchers have not isolated all cannabinoids, nor have researchers explored all of the cannabinoids' health benefits.[96] Rather, the proper § 101 inquiry evaluates whether the patent directs its claims towards patent-ineligible concepts like "[l]aws of nature, natural phenomena, and abstract ideas."[97]

B. The Lack of Documentary Evidence Adversely Impacts Consumers

Cannabis is not the only commodity that currently stumps the PTO. Software patents have similar problems with overly broad claims purporting to violate the prior art.[98] However, the

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94 42 U.S.C. §§ 2181(a), 2182 (2018); *see also* Whistler Corp. v. Autotronics, Inc., No. CA3-85-2573-D, 1988 U.S. Dist. LEXIS 17302, at *4 (N.D. Tex. July 28, 1988) ("Unless 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."). *But see* 21 U.S.C. § 841(a) (2018) (prohibiting manufacturing, distributing, dispensing, and possessing a controlled substance, such as marijuana).

95 *Compare Chakrabarty*, 447 U.S. at 309 (discussing the patentability of non-naturally occurring compositions of matter), *with* Funk Bros. Seed Co. v. Kalo Inoculant Co., 333 U.S. 127, 131 (1948) (holding that a vaccine that aggregated bacteria strains is unpatentable because the mere aggregation is not a new composition of matter).

96 *See* E.M. Mudge, S.J. Murch & P.N. Brown, *Chemometric Analysis of Cannabinoids: Chemotaxonomy and Domestication Syndrome*, 8 SCI. REP. 1, 1 (2018).

97 Alice Corp. v. CLS Bank Int'l, 573 U.S. 208, 216 (2014) (internal quotation marks omitted).

98 *See* Arti K. Rai, John R. Allison & Bhaven N. Sampat, *University Software Ownership and Litigation: A First Examination*, *in* PERSPECTIVES ON PATENTABLE SUBJECT MATTER 336, 346 (Michael B. Abramowicz, James E. Daily & F. Scott Kieff eds., 2014). Additionally, independent organizations have attempted to create a database for third parties to utilize for independent prior art submissions to invalidate overly broad software patents. *See* Gene Quinn & Steve Brachmann, *MIT Prior Art Archive: An Overstated Solution to Patent Examination*, IPWATCHDOG (Nov. 6, 2018) https://www.ipwatchdog.com/2018/11/06/mit-prior-art-archive-

cannabis industry differs from the software space because, unlike software, cannabis use dates back millennia.[99] Thus, determining the bounds of cannabis's prior art becomes increasingly more confusing in light of cannabis's recent fifty-year prohibition.

Regulations deprived the cannabis industry of prior art for years. Recent developments—such as the Farm Bill or the FDA's approval of Epidiolex[100]—produced optimism. This optimism prompted inventors to take advantage of deregulation by submitting an influx of cannabis-related patents to the PTO.[101] The increase in patent applications brings patent viability into question because many cannabis patents make broad claims that appear to violate §§ 102 and 103.

Patenting cannabis strains creates problems for inventors because it is difficult to prove the strain's novelty without documentary evidence.[102] The strain may have been sold in commerce—albeit illegally—for years, but due to the strain's lack of public disclosure, patent examiners cannot invalidate the patent based on a prima facie showing of obviousness.[103] Inadequate public disclosure makes invalidating cannabis patents under §§ 102 and 103 difficult because inventors cannot produce prior-art evidence.[104]

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overstated-solution-patent-examination/id=102666/ [https://perma.cc/8LEJ-YM5R]. Similarly focused organizations have attempted to create prior art databases within the cannabis industry as well. *See How Does Kannapedia.net Help Prove Prior Art?*, MED. GENOMICS https://www.medicinalgenomics.com/kannapedia-net-help-prove-prior-art/ [https://perma.cc/7HYU-T79V] (last visited Feb. 7, 2021).

99 *See* Vera Rubin, *Cross-Cultural Perspectives on Therapeutic Uses of Cannabis*, *in* THE THERAPEUTIC POTENTIAL OF MARIHUANA 1, 2–6 (Sidney Cohen & Richard C. Stillman eds., 1976).

100 Alva C. Mather, *Remaining CBD Hurdles for Food and Drink Manufacturers*, LAW360 (May 6, 2019, 3:26 PM), https://www.law360.com/articles/1156431/remaining-cbd-hurdles-for-food-and-drink-manufacturers [https://perma.cc/4JSM-VHC9].

101 *See id.*; *see also* Bultman, *supra* note 65 (discussing the increase in cannabis patents).

102 Emily Pyclik, *Obstacles to Obtaining and Enforcing Intellectual Property Rights in the Marijuana Industry*, 9 AM. U. INTELL. PROP. BRIEF 26, 44 (2017).

103 *See, e.g.*, *In re* Peterson, 315 F.3d 1325, 1329 (Fed. Cir. 2003) ("A *prima facie* case of obviousness typically exists when the ranges of a claimed composition overlap the ranges disclosed in the prior art.").

104 *See* Abbott Labs. v. Sandoz, Inc., 544 F.3d 1341, 1345 (Fed. Cir. 2008). *But see* 2A CHISUM ON PATENTS § 6.02(5)(a) (2019) (stating "[p]ublic use means use of the product or process in its natural and intended way—even if the invention may in fact be hidden from public view with such use" (internal quotation marks omitted)).

Cannabis research slowed after the CSA designated marijuana as a Schedule I substance.[105] This pushed cannabis use towards becoming an inherently private affair, which limited the extent of cannabis research. Due to the lack of competition in the space, organizations are managing to obtain broad patents with less regard for the considerations demanded by §§ 102 and 103. For instance, in 1996, the University of Mississippi obtained a patent that claimed the use of THC to treat pain, anxiety, and loss of appetite, which mirrors cannabis's long understood medical applications.[106] More recently, the PTO issued its first cannabis plant patent,[107] the claims of which capture fifty to seventy percent of the strains currently sold on the market.[108]

Problems regarding the prior art within the cannabis industry are beginning to crystallize in the form of litigation. In *Insys Development Co. v. GW Pharma Limited and Otsuka Pharmaceutical Co.*, Insys commenced an IPR to invalidate GW Pharma's patent under § 103.[109] Insys argued that claims 1–13 in U.S. Patent No. 9,066,920 violated § 103's nonobviousness requirement.[110] The claims targeted a method of administering 400 mg cannabidiol (CBD) to treat epilepsy.[111] The PTAB first addressed the use of the term "partial seizure" in the claims and concluded that it was unnecessary to construe the term to determine patentability.[112]

Insys submitted a medical study from 1980 in which epileptic patients received 200–300mg of CBD to reduce the occurrence of seizures.[113] Insys also submitted a study from

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105 21 U.S.C. § 812(c) (2018); *see supra* subpart I.B.

106 *Compare* U.S. Patent No. 5,508,037 (issued Apr. 16, 1996) (discussing University of Mississippi's claims for using cannabis to treat pain, anxiety, and loss of appetite), *with* MITCHELL EARLEYWINE, UNDERSTANDING MARIJUANA: A NEW LOOK AT THE SCIENTIFIC EVIDENCE 9–12 (2002) (describing how ancient civilizations in China, India, Egypt, South Africa, and Rome used cannabis to treat pain, nervousness, and poor appetite).

107 Melanie S. Rowand & Eileen M. McMahon, *Cannabis: Regulatory and IP Landscape for Food and Agribusiness in Canada—A Legal Perspective*, 23 DRAKE J. AGRIC. L. 67, 73 (2018).

108 BROUGHER, *supra* note 74 (discussing the first cannabis plant patent); Brett M. Schuman, Cynthia Lambert Hardman, Olivia D. Uitto & David L. Simson, *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/AL7V-YJE6] (same).

109 Insys Dev. Co. v. GW Pharma Ltd., No. IPR2017-00503, at 2 (P.T.A.B. Jan. 3, 2019).

110 *Id.*

111 *Id.* at 4.

112 *Id.* at 10–11.

113 *Id.* at 16–17.

2009, which involved administering 10 mg of THC and 600 mg of CBD to observe the drugs' combined effects on regional brain function.[114] Additionally, Insys submitted a previously filed patent demonstrating the safe co-administration of tetrahydrocannabivarin (THCV) and CBD; however, this patent did not discuss treatment of seizures, and the court rejected the patent as established prior art.[115]

Insys argued that GW Pharma's patent made claims that were obvious to a person reasonably skilled in the art because GW Pharma merely increased the dosage from the first submitted study, and it failed to prove a safer method of administering the drug based on the second submitted study.[116] The PTAB found claims 1 and 2 obvious under § 103 because a person reasonably skilled in the art would have considered treating epilepsy with 400 mg of CBD based on the prior art.[117] However, with respect to Claims 3–13, the PTAB agreed with GW Pharma that Insys failed to provide evidence that the Claims were obvious.[118] The PTAB found that Insys's evidence did not address GW Pharma's claim limitations, such as using isolated CBD, or combining the CBD with THCV to treat *partial seizures*.[119]

Insys provides a forecast for future third-party challenges to cannabis patents. As more companies enter the cannabis space, patent challenges under §§ 102 and 103 will likely increase.

C. Creating an Environment Ripe for Future Litigation

Cannabis patents are not immune from enforcement and infringement actions. The mounting number of cannabis patents filed with the PTO foreshadows the potentially high amount of litigation to come. Equally compelling, a growing number of major U.S. law firms recently established practice groups that cater specifically to the cannabis industry, whereas national accounting firms have not adopted practices for advising the cannabis industry.[120]

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114 *Id.* at 18.
115 *Id.* at 16 n.13, 30–31.
116 *Id.* at 19–20.
117 *Id.* at 22.
118 *Id.* at 29–31.
119 *Id.*
120 *Compare* Stephanie Russell-Kraft, *More Law Firms Rolling with Cannabis Ventures*, BLOOMBERG LAW (Aug. 9, 2018, 7:04 AM) https://biglawbusiness.com/more-law-firms-rolling-with-cannabis-ventures [https://perma.cc/9XGP-83C3] (discussing how major U.S. law firms have established a growing cannabis prac-

United Cannabis filed the first cannabis infringement action against Pure Hemp Collective in early 2019.[121] Pure Hemp denied the infringement allegation and asserted that United Cannabis's patent was unenforceable under § 101.[122] United Cannabis's patent claimed an "extract comprising a mixture of at least 95% total cannabinoids, and at least one terpene/flavonoid."[123] Pure Hemp argued that this claim violated § 101 because it covered a naturally occurring phenomenon.[124] The District Court declined to grant Pure Hemp's motion for summary judgment because Pure Hemp failed to show that United Cannabis's liquid CBD formula existed in nature.[125] Thus, the liquid formulation satisfied the *Alice* test.[126] However, the court declined to answer whether the patent satisfied the requirements set forth in §§ 102 and 103.[127]

United Cannabis, like *Insys*, provides insight into the outlook for future cannabis litigation. Current and prospective industry participants will likely continue to take advantage of the patent law system to bolster their patent portfolios.

III
POSSIBLE SOLUTIONS FOR INTEGRATING CANNABIS INTO PATENT LAW'S FRAMEWORK

Cannabis does not fit neatly into the patent system. As such, Congress or the PTO must provide guidance to the cannabis industry, as the PTO recently did for trademarks.[128] Continuing to grant overly broad patents impairs certainty regarding a patent's validity, ensures a highly litigious future for the industry, and increases costs for consumers.

One seamless approach to creating greater certainty around cannabis patents could be achieved through changing the claim structure for cannabis patents. Requiring the use of structural claims, which limit the patent to a particular imple-

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tice), *with Providing Services to Businesses in the Marijuana Industry*, AM. INST. CERTIFIED PUB. ACCT. https://www.aicpa.org/advocacy/state/marijuana.html [https://perma.cc/F4E9-PJEL] (last visited Feb. 7, 2020) (stating that "CPAs are looking to their state boards of accountancy" for guidance).

121 Bultman, *supra* note 65; *see* United Cannabis Corp. v. Pure Hemp Collective Inc., No. 18-cv-1922-WJM-NYW, 2019 U.S. Dist. LEXIS 66092, at *4 (D. Colo. Apr. 17, 2019).

122 *United Cannabis Corp.*, 2019 U.S. Dist. LEXIS 66092, at *4–5.

123 *Id.* at *3.

124 *Id.* at *15.

125 *Id.* at *16.

126 *Id.* at *17.

127 *Id.*

128 U.S. PATENT & TRADEMARK OFFICE, *supra* note 89, at 3.

mentation, in addition to using functional claims, could narrow the patents' scope and prevent undue market exclusivity.[129] Structural claims limit the patents' scope because structural claims are directed at what the invention does. Combining structural claims with functional claims thereby constrains the patents' scope.[130] The PTO should provide guidance to inventors to include both claims in cannabis patents because structural claims provide greater clarity to the invention's purpose. This change mitigates the lack of prior art by forcing inventors to clearly define the invention, necessitating a careful contemplation of the pertinent art, and more appropriately comports with patent law's goals. Drafting patents with claims that discuss how to implement the invention, in addition to the invention's function, also bolsters the patents' strength under §§ 101, 102, 103, and 112.[131]

Changing the way cannabis patents are drafted may be effective if implemented *pari passu* with a broader definition of cannabis's field. A challenger can invalidate a patent under §§ 102 and 103 when the challenger proves that the invention is obvious or is not novel to a person employed with the relevant expertise *in a particular field*.[132] Given cannabis's multitude of applications, stiffer claim requirements may lack the needed bite if the analogous art is interpreted too narrowly. Factfinders should take a broader approach when evaluating cannabis patent claims and invalidate claims when they are obvious or not new to the cannabis industry generally (not just a particular field). This approach comports with the broad approach the PTO typically employs at the claim prosecution phase.[133]

As seen in *United Cannabis*, the court left the prior art inquiry open.[134] In doing so, the court permitted Pure Hemp to provide evidence as to whether a person reasonably skilled in

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129 *See* Mark A. Lemley, *Software Patents and the Return of Functional Claiming*, 2013 WIS. L. REV. 905, 919 (2013).

130 *See* MARTIN J. ADELMAN, RANDALL R. RADER, JOHN R. THOMAS & HAROLD C. WEGNER, CASES AND MATERIALS ON PATENT LAW § 11.2(c), at 670–71 (2d ed. 2003).

131 *See* Michael D. Stein, *How Structural Claim Limitations Can Save Software Patents*, LAW360 (Feb. 9, 2016, 11:09 AM), https://www.bakerlaw.com/files/uploads/Documents/News/Articles/INTELLECTUAL%20PROPERTY/2016/Stein-Law360-02-09-2016.pdf [https://perma.cc/SDK4-QQ7D].

132 *See* ADELMAN, RANDALL, THOMAS & WEGNER, *supra* note 130, § 8.2, at 557, 561.

133 *See*, *e.g.*, *In re* Yamamoto, 740 F.2d 1569, 1571 (Fed. Cir. 1984) (stating that "[t]he PTO broadly interprets claims during examination of a patent application").

134 *See* United Cannabis Corp. v. Pure Hemp Collective Inc., No. 18-cv-1922-WJM-NYW, 2019 U.S. Dist. LEXIS 66092, at *17 (D. Colo. Apr. 17, 2019).

the art could have determined if United Cannabis's patent failed to satisfy § 102 or § 103's requirements. This provides future inventors some incentive to narrow a patent's claims to ensure courts will enforce the patent and bring a swift end to the patent's litigation. Indeed, some practitioners suggest that focusing on the patent claim's depth protects patents from failing Title 35's requirements.[135] Failure to focus on claim depth may result in partial invalidation of claims, as seen in *Insys*, or could result in a wholly invalid patent.

Imposing stiffer claim requirements with a broader approach to the pertinent art may provide a long-term solution for integrating cannabis inventions into the patent system. However, given the lack of prior art, short-term problems may fester. Though limited, current litigation surrounding cannabis patents may provide a workable framework if courts add additional steps to the factfinder's analysis. By relying on *Alice* and *Mayo*, the district court in *United Cannabis* implicitly provided fodder for future litigants in the cannabis space by providing a prospective approach for challenging a patent's validity.[136] The Supreme Court invalidated the patent in *Mayo* because the patent concerned conventional activity already engaged in by the scientific community.[137] Future courts and examiners should use the *Mayo* and *Alice* tests to evaluate whether the claim concerns a prevalent use among cannabis consumers. This approach could permit courts to peer beyond the traditional forms of documentary evidence used in patent validity cases and would help courts circumvent the problems created by cannabis's once-illicit nature. This approach is not without precedent.

The Federal Circuit appeared to use a form of this approach in *Takeda Pharmaceuticals U.S.A., Inc. v. West-Ward Pharmaceutical Corp.*, when the Federal Circuit evaluated whether a generic company could market a generic form of Takeda's drug that targeted prophylaxis of gout flares.[138] The Federal Circuit declined to find for Takeda because physicians that treat gout flares routinely prescribe other treatments, and these physicians rarely prescribe colchicine.[139]

Furthermore, in *EmeraChem Holdings, L.L.C. v. Volkswagen Group of America, Inc.*, Volkswagen sued EmeraChem

135 BROUGHER, *supra* note 74, at loc. 1072.
136 *See United Cannabis Corp.*, 2019 U.S. Dist. LEXIS 66092, at *17.
137 Mayo Collaborative Servs. v. Prometheus Labs., 566 U.S. 66, 73 (2012).
138 785 F.3d 625, 627–28, 638 (Fed. Cir. 2015).
139 *Id.* at 633.

to invalidate EmeraChem's patent.[140] Volkswagen argued that the invention violated § 102 because the inventor failed to show that it did not rely on prior art.[141] The Federal Circuit agreed with Volkswagen that the inventor's declaration failed to satisfy § 102(e).[142] However, the Court noted that "[i]n certain cases, we have recognized that even non-documentary, circumstantial evidence may sufficiently corroborate [the prior art]."[143] In formulating this statement, the Court cited cases in which the Federal Circuit accepted independent circumstantial evidence to corroborate prior art for patents challenged under § 102.[144] The Federal Circuit determined that the PTAB did not err in considering Volkswagen's circumstantial evidence as evidence of prior art.[145]

Thus, courts are willing to accept circumstantial evidence to invalidate a patent and often accept non-traditional prior art references for patent challenges arising under §§ 102 and 103.[146] This approach serves public policy considerations. Using non-traditional materials to inform factfinders on "the level of ordinary skill in the art to which the invention pertained" is necessary given the dearth of published materials examining cannabis.[147] Moreover, it affords the factfinder greater discretion to look at the relevant use when evaluating the prior art, and the approach has proved effective with respect to plant patents.[148]

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140 859 F.3d 1341, 1344 (Fed. Cir. 2017).

141 *Id.* at 1345.

142 *Id.* at 1348.

143 *Id.* at 1347.

144 *See id.* at 1348 (citing *In re* Jolley, 308 F.3d 1317, 1328 (Fed. Cir. 2002)).

145 *Id.*

146 *See* Newell Cos. v. Kenney Mfg. Co., 864 F.2d 757, 766 (Fed. Cir. 1988), *cert. denied*, 493 U.S. 814 (1989); *see also* Sudden Valley Supply L.L.C. v. Ziegmann, No. 4:13-CV-53-RLW, 2016 U.S. Dist. LEXIS 76380, at *17 (E.D. Mo. June 13, 2016) (relying on circumstantial evidence to invalidate a trap patent claim); Grant St. Grp., Inc. v. Realauction.com, L.L.C., No. 2:09-cv-01407-DWA, 2012 U.S. Dist. LEXIS 57813, at *28–29, *32–33 (W.D. Pa. Feb. 23, 2012) (using email exchanges and advertisements to deny a motion for summary judgment and invalidate prior art), *adopted*, No. 9-1407, 2012 U.S. Dist. LEXIS 57820 (W.D. Pa. Apr. 25, 2012); Transocean Offshore Deepwater Drilling, Inc. v. Globalsantafe Corp., 443 F. Supp. 2d 836, 852 (S.D. Tex. 2006) ("Circumstantial evidence about the inventive process, alone, may also corroborate.").

147 Thomas & Betts Corp. v. Litton Sys., Inc., 720 F.2d 1572, 1581 (Fed. Cir. 1983).

148 *See, e.g.*, Kim Bros. v. Hagler, 167 F. Supp. 665, 671 (S.D. Cal. 1958) (holding that "asexual" reproduction of a plant created a new plant variety and thus did not violate a previous patent for the original plant), *aff'd*, 276 F.2d 259 (9th Cir. 1960).

Normalization of a more discretionary approach may be useful in particularly tough cases, where the lack of prior art impacts the case's outcome. *Insys* demonstrated the PTAB's willingness to accept previous publications—based on small studies—to invalidate patent claims.[149] Further, *Insys* attempted to overcome a narrow claim analysis by presenting an exhaustive record regarding the meaning of "partial seizure" and its insufficiency as a claim limitation in light of the prior art's limited nature.[150] However, the PTAB followed an unworkable standard for the cannabis industry by upholding claims where the prior art did not comport with a rigid claim construction. The PTAB permitted Claims 3–13 to stand on the basis that the accepted prior art only demonstrated that CBD and THCV could be used to treat some form of epilepsy instead of partial seizures.[151] Thus, *Insys* provides limited guidance for cases where a patent claims a well-established form of cannabis, such as the BioTech patent discussed in note 86. In cases such as these, greater discretion for factfinders may be useful to demonstrate how a person reasonably skilled in the art would view the patents' claims.

This approach also comports with the PTO's standard used for claim prosecution mentioned in Part II. Adopting this approach better serves the public interest because it prevents patents from receiving protection for unintended claims.[152] In *Insys*, the PTAB noted that it was not necessary to construe the term "partial seizure" because "[c]laim terms need only be construed to the extent necessary to resolve the controversy."[153] However, claim construction is a complicated art, and several factors—including expert testimony—inform factfinders on the claims' proper meaning.[154] A broader approach to claim construction might have produced a different outcome in *Insys* because the PTAB could have considered the expert witness's testimony that partial seizures could be construed to mean general seizure.[155] Instead of focusing on the modern con-

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149 *See* Insys Dev. Co. v. GW Pharma Ltd., No. IPR2017-00503, at 5 (P.T.A.B. Jan. 3, 2019).

150 *See id.* at 8–11.

151 *Id.* at 16 n.13, 29–31.

152 *See In re* Yamamoto, 740 F.2d 1569, 1571 (Fed. Cir. 1984).

153 *Insys Dev. Co.*, No. IPR2017-00503, at 10–11 (internal quotation marks omitted) (quoting *Wellman, Inc. v. Eastman Chem. Co.*, 642 F.3d 1355, 1361 (Fed. Cir. 2011)).

154 *See* Peter S. Menell, Matthew D. Powers & Steven C. Carlson, *Patent Claim Construction: A Modern Synthesis and Structured Framework*, 25 BERKELEY TECH. L.J. 711, 738–44 (2010).

155 *See Insys Dev. Co.*, No. IPR2017-00503, at 10–11.

struction of partial seizures versus epilepsy, the PTAB could have considered the circumstances in which the studies referenced by Insys were conducted. Due to the lack of cannabis availability, researchers might focus on broader conditions in order to develop more ubiquitous treatments. As such, looking at the totality of the circumstances provides a more fitting approach for cannabis claim construction because it permits the factfinder to consider how a person skilled in the art would interpret claims.

One comparative approach could be the strategy the European Patent Office (EPO) used when it evaluated neem tree patents in the 1990s.[156] In 1994, a company patented the use of an herb that prevented fungal growth.[157] Local residents protested the patent grant because the residents used the herb in this manner for centuries and the residents claimed that the company pirated the herb's use.[158] The EPO revoked the patent after public outcry and after a local company provided evidence that the company used a different neem-based fungicide for decades.[159] Perhaps the PTO could adopt the EPO's reasoning to create a carve-out for cannabis-related IPRs. The PTAB should accept less traditional disclosures or forms of commercial sales when evaluating a claim's level of obviousness or novelty. This approach could aid the PTAB in evaluating cannabis patents that purport to cover substantial portions of the market.

Factfinders should consider multiple factors when construing claims, particularly if the patent fails to specify the invention's intended application.[160] It is not uncommon for factfinders to use multiple extrinsic factors in construing claims, including expert testimony, dictionaries, treatises, and inventor testimony.[161] Placing greater emphasis on these factors aids factfinders in determining whether the patents' claims

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156 *See* Ulrike Hellerer & K.S. Jarayaman, *Greens Persuade Europe to Revoke Patent on Neem Tree . . .* , 405 NATURE 266, 266 (2000).

157 *Id.* at 266–67.

158 *See id.*

159 *See id.*

160 GW Pharma's patent covers the drug Epidiolex, which is currently marketed to cover "treatment of seizures associated with Lennox-Gastaut syndrome or Dravet syndrome." *See* U.S. FOOD & DRUG ADMIN., EPIDIOLEX PRODUCT LABEL (2018), https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/210365lbl.pdf [https://perma.cc/NBQ8-WNLT]. However, the "'920 Patent involve[d] the use of cannabinoids in the treatment of *epilepsy*, and more particularly, generalized or partial seizures." Insys Dev. Co. v. GW Pharma Ltd., No. IPR2017-00503, at 4 (P.T.A.B. Jan. 3, 2019) (emphasis added).

161 Menell, Powers, & Carlson, *supra* note 154, at 741 chart 7.

accurately reflect a novel and nonobvious invention in the absence of documentary evidence. This practice should become the standard because it would help integrate cannabis patents into the patent system more smoothly.

CONCLUSION

The lack of prior art surrounding cannabis produces deleterious outcomes for inventors and consumers alike. Patent protection may serve inventors' interests, but the lack of certainty regarding a patent's validity impacts the industry generally by incentivizing early entrants to make broad patent claims. Placing more narrow restrictions on claims and allowing factfinders to look broadly at analogous art may produce more beneficial outcomes by enabling inventors to clearly state an invention's purpose.

Constraining patent claims to more narrow purposes would enhance the certainty surrounding a patent's validity. The *Alice* decision dictates that ambiguous patents fall outside § 101.[162] Given the significant financial risk of losing patent protection, cannabis inventors and manufacturers should shift their focus toward including structural claims to ensure patent protection. This forces inventors to improve the cannabis industry by making truly novel inventions as opposed to capitalizing on the lack of published materials. Consumers would also benefit from the shift in drafting practices. Rejecting broad patents will lead to more available products in a competitive marketplace. However, inventors will continue to have an incentive to create innovative products if the inventor can submit a well-claimed patent that satisfies patent law's requirements.

The cannabis industry will continue to grow, and inventors in the space will continue to seek patent protection. To best serve the industry's long-term success and consumers' interests, something must be done to quell the uncertainty around patents in the space. Failing to do so uproots an otherwise budding industry.

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162 *See* Alice Corp. v. CLS Bank Int'l, 573 U.S. 208, 217 (2014).