

Emerging Patent Issues In The Cannabis Industry

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Thirty states currently permit some form of legal marijuana use, including legal use of cannabis by adults for recreational purposes in eight states and the District of Columbia. To date, there has been relatively little patent-related activity for a market that is predicted to be valued at \$21 billion by 2020.[1] But that may be changing.

As the state-legal cannabis market continues to expand into a multi-billion dollar industry, market participants and others are seeking to build cannabis patent portfolios. In August 2015, the first U.S. utility patent to a hybrid cannabis plant was issued, heralding a new area for cannabis patenting. As industry players aggressively build patent portfolios around their products, including marijuana strains, a cannabis patent war is likely on the horizon. In this article, we preview some of the potentially unique issues associated with patenting the cannabis plant, and enforcing those patents.

Brief Background on Cannabis and Cannabis Patents

The cannabis plant contains over 400 chemicals, including more than 60 cannabinoids. The most common cannabinoids in the plant include tetrahydrocannabinol (“THC”), which is responsible for the psychoactive effects of the plant; and cannabidiols (“CBDs”), which are non-psychoactive components thought to have medical potential. The plant also includes a number of terpenes, which provide cannabis with its characteristic scents. Common terpenes found in the plant include myrcene, linalool and limonene. The ratios of THC, CBDs, terpenes and other compounds differentiate one strain of cannabis from another.

Federal law continues to classify marijuana as a Schedule I drug under the Controlled Substances Act, which means that the government currently deems the drug to have no accepted medical use and a high potential for abuse. Interestingly, though, the federal government itself owns U.S. Patent No. 6,630,507, which relates to the use of cannabinoids in treating certain diseases, such as neurodegenerative disease in the central nervous system. As the '507 patent shows, there is nothing inherently illegal about obtaining patent protection over marijuana and marijuana-related subject matter. As with any other subject matter, the patent office will typically grant a patent if the subject matter is found to be novel,



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useful and nonobvious.

Plant Patents Versus Utility Patents

In August 2015, U.S. Patent No. 9,095,554 (the “’554 patent”), entitled “Breeding, Production and Use of Specialty Cannabis,” was issued to BioTech Institute LLC. This patent broadly claims cannabis strains with a CBD content greater than 3 percent plus a terpene profile where myrcene is not the dominant terpene. According to some reports, BioTech’s broad cannabis patents could cover 50 to 70 percent of all cannabis strains on the market today.

With the United States Patent and Trademark Office granting the ’554 patent, the first cannabis utility patent, growers can now seek patent protection of cannabis plants in utility patent applications. Until the issuance of the ’554 patent, it seemed that growers were restricted to plant patents for protecting their inventions, which offer limited protection. While issued plant patents offer similar protection to patentees as issued utility patents — preventing others from asexually reproducing the plant, and from using, selling, offering for sale or importing the claimed plant for the same length of time — 20 years (not including any patent term adjustments), the main disadvantage of a plant patent is that it is limited to a single claim.

By being limited to a single claim, plant patents are restrictive in what they protect. For example, consider PP27,475 (the “’475 plant patent”), where the single claim is:

Claim 1. A new and distinct cultivar of ‘Cannabis’ plant, as shown and described.

For this single patent claim to comply with the written description requirement of U.S. patent law, the patent specification must sufficiently describe the claimed plant. For example, in the ’475 plant patent, the plant is described in the specification as:

‘Equadorian Sativa’ has been shown by laboratory testing by Steephill Labs to contain cannabinoid CBG-A at 2.49 mg/g, tetrahydrocannabinol THC-A at 139.46 mg/g, THC at 2.24 mg/g and cannabinoid CBC-A at 1.75 mg/g. ‘Equadorian Sativa’ cannabinoid content is dominated by its high content of THC (2.24 mg/g) and THC-A (139.46 mg/g). There are small levels of Beta Myrcene, Beta Caryophyllene and Linalool, but the Limonene level is extraordinarily high at a level of 4.53, 10 to 20 times the usual range. This sets ‘Equadorian Sativa’ apart from other varieties in its odor, the effects on mood and mentation and its medical qualities.

The ’475 plant patent specification describes the plant by specific amounts of THC-A, CBG-A, THC and CBC-A. In contrast, the ’554 utility patent demonstrates that patentees are able to claim and define a cannabis plant not just by specific chemical composition amounts, but by ranges of values. The ’554 utility patent claims a hybrid cannabis plant based on ranges of chemical composition; for example, a CBD content greater than 3 percent and a terpene oil content greater than about 1.0 percent by weight: Claim 1. A hybrid Cannabis plant, or an asexual clone of said hybrid Cannabis plant, or a plant part, tissue, or cell thereof, which produces a female inflorescence, said inflorescence comprising: a) a BT/BD genotype; b) a terpene profile in which myrcene is not the dominant terpene; c) a terpene oil content greater than about 1.0% by weight; and d) a CBD content greater than 3%; wherein the terpene profile is defined as terpinolene, alpha phelladrene, beta ocimene, careen, limonene, gamma terpinene, alpha pinene, alpha terpinene, beta pinene, fenchol, camphene, alpha terpineol, alpha humulene, beta caryophyllene, linalool, cary oxide, and myrcene, and wherein the terpene oil content is determined by the additive content of the terpenes in the terpene profile; and wherein the terpene contents and CBD content are measured by gas chromatography-flame ionization detection (GC-FID) and calculated based

on dry weight of the inflorescence; wherein a representative sample of seed producing said plants has been deposited under NCIMB Nos. 42246, 42247, 42248, 42249, 42250, and 42254.

Building a Cannabis Patent Portfolio

The '554 utility patent serves as a model of how cannabis plants can be protected by more than a single claim of a plant patent. Using the utility patent approach pioneered by the '554 patent, a patentee may gain broader protection in claiming the chemical ranges of the cannabis plant. Not only is a competitor potentially excluded from reproducing, using, selling, offering to sell or importing the specific plant, but also any plant engineered to be a close approximation. A sole plant patent (limited to one claim of a specific plant) may not prevent a competitor from engineering a close, but noninfringing plant. Thus a competitor could enter the market selling a similar plant, leaving the patentee with little recourse.

In developing a patent portfolio to protect a new type of plant, utility patent applications claiming cannabis plants are attractive to growers and plant engineers. Protecting commercially valuable cannabis plants warrants a patent estate with more than single-claim plant patents.

Impact of Availability of Prior Art

With the '554 utility patent serving as a model for drafting cannabis-related patent claims, an avalanche of utility applications that claim cannabis plants not by specific chemical make-up, but by ranges of their chemical composition, could hit the USPTO. However, patent examiners charged with assessing the patentability of these claims will face a limited body of prior art to help discern patentable subject matter from unpatentable subject matter.

The unique legal status of cannabis creates a dearth of reliable sources of prior art compared, for example, to more mature industries such as software and pharmaceuticals. As such, patent examiners will have to grapple with this limited body of prior art when ascertaining whether cannabis plant claims are new, novel and nonobvious. Some third parties are attempting to address this void. For example, the Open Cannabis Project is building a database of genetic sequences of known cannabis plants, which can act as a source of prior art. But while genetic sequence information is available, the corresponding chemical composition of the plant is limited or missing. With just the sequences of the plants available and without sufficient data on their corresponding chemical composition, the USPTO may issue cannabis patents with hidden problems such as lack of novelty, obviousness and inherent anticipation. Further complicating this issue is the complex makeup of the cannabis plant, which as noted above, contains over 400 chemical compounds.

Without a solid body of prior art of the chemical compositions of available cannabis plants, a patent examiner may have difficulty locating prior art bearing on the question of whether a particular plant profile is novel, and in correlating claimed chemical composition ranges with published cannabis plant sequences. Thus, whether a given plant defined by ranges of chemical compositions is patentable under 35 U.S.C. § 102 or nonobvious under 35 U.S.C. § 103 may be unknown at the examination stage.

The trend of growers and engineers using utility patents to provide protection of cannabis plants by claiming chemical composition ranges could trigger a wave of patents being issued that have been examined with a limited body of prior art. A challenger could invalidate such a patent by presenting evidence that a previously known cannabis plant has the same chemical profile. Thus, cannabis patent portfolios may be vulnerable to prior art challenges by competitors. As more industry players invest in utility patents to create patent estates, this state of play may leave patentees and competitors unsure

about the true strength and robustness of a given patent portfolio.

Enforceability Issues

To date there has been very little patent litigation involving cannabis patents. Some commentators have suggested that cannabis' illegality under the Controlled Substances Act could mean that patents covering cannabis would be deemed unenforceable in the federal courts. But unlike patent law in other jurisdictions (e.g., the E.U.), there is no morality or legality requirement for patent eligibility in United States patent law. Long ago, courts interpreted 35 U.S.C. § 101 as requiring that an invention "should not be frivolous or injurious to the well-being, good policy or sound morals of society,"[2] but this so-called "moral utility doctrine" has since been repudiated.[3] Indeed, patents have been granted (if not enforced) on "useful" but currently illegal (or highly regulated) inventions like high-capacity ammunition magazines, fully-automatic machine guns, self-driving vehicles, genetic engineering of humans, etc. Pharmaceutical companies regularly obtain patent protection for highly addictive opioids, which the federal government acknowledges contribute to a "public health emergency." About the closest U.S. patent law comes to issues of legality is 35 U.S.C. § 181, which permits U.S. defense agencies to mandate secrecy for inventions related to, for example, nuclear weapons.

Other have suggested that there may be practical problems in litigating cannabis patents: the effect of legally binding admissions to growing or selling marijuana in complaints, answers or discovery, and difficulties in presenting physical evidence (e.g., the accused cannabis plants) in federal court. As of now, however, no judge or jury has yet been asked to enforce a patent covering cannabis varieties, and the legal and practical aspects of enforcing them are still unresolved.

Conclusion

Members of the budding state-legal cannabis industry need to tread carefully. As growers and other innovators start obtaining patent protection with plant and utility patents, the lack of prior art may lead to issuance of overbroad patents that pose serious risks to other market participants. But patentees also need to be concerned that a plant variety could be lurking out there that a challenger could use to invalidate their patent, or attack their patent portfolio. And enforceability of cannabis patents remains an open question with no controlling precedent to rely on.

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[1] <http://money.cnn.com/2016/11/09/news/economy/marijuana-legalization-sales/index.html>.

[2] Lowell v. Lewis, 15 F. Cas. 1018 (No. 8568) (C.C.D. Mass. 1817).

[3] See, e.g., Juicy Whip Inc. v. Orange Bang Inc., 185 F.3d 1364, 1366-68 (Fed. Cir. 1999); see also MPEP § 706.03(a) (disallowing rejections "based on grounds that the invention is frivolous, fraudulent or against public policy").