Cannabis Plant Protection

Updated March 2017



Types of Plant Protection

Generally speaking, three types of intellectual property protection available for plants:

- ♦ Utility Patent
- **♦ Plant Patent**
- **♦ PVPA Certificate**



Utility Patent

"Whoever invents or discovers any **new and useful process, machine, manufacture, or composition of matter** . . . may obtain a patent therefor . . . "

- Generic patent regime covering all inventions
- Plants are not treated differently than other subject matter for a utility patent
- Greatest breadth of possible protection, however highest barriers to qualify



Utility Patent - Basics

- Administered by the U.S. Patent & Trademark Office (USPTO)
- ◆ USPTO fees ≅ \$3,000 \$5,000, plus maintenance fees to keep patent active at 3.5, 7.5, 11.5 years
- Attorney fees ≅ \$5,000 \$15,000
- ~15-18 months before application first reviewed
- ~24-36 months before typical application granted



Utility Patent - Protection

- 20 years from the date of filing the application
- Right to exclude others from making, using, selling, offering for sale, and importing invention
- A plant variety can be described generically by reference to its defining characteristics – the biggest advantage compared to a plant patent
- Plant itself can be claimed, plus plant products, uses of plant, methods of creating plant, etc.



Utility Patent - Requirements

- ❖ <u>Utility</u>: a specific, substantial, and credible use
- Novelty: cannot have previously existed, or been on sale by applicant for over a year
- Non-obviousness: cannot be obvious in view of what existed beforehand
- Written description: application must provide sufficient disclosure describing the plant variety
- * Enablement: one must be able to produce and use the claimed plant without undue experimentation



Non-Obviousness Requirement

Poses the greatest hurdle for plant inventions. Ask:

- Would the particular characteristics of the claimed plant variety have been predictable?
- Would creating a variety with the particular characteristics have been obvious to try?
- When creating the variety, would there have been an expectation of success?



Non-Obviousness Examples

- A high-CBD strain obtained by crossing two other high-CBD strains probably obvious
- A high-yielding strain obtained by crossing two low-yielding strains may be non-obvious
- A strain with multiple characteristics appearing together for the first time – likely non-obvious

The more unique and distinct characteristics a strain has, the more likely it will be found non-obvious



What Could Qualify for Protection?

Examples of possible strain characteristics:

- Cannabinoid profile/levels
- Terpene profile/levels
- Growth characteristics/hardiness
- Improvement of flower quality/yield
- Disease/insect/drought/salt tolerance
- Improvement of carbohydrates/amino acids
- Increases in secondary plant products
- Male sterility
- Stable and heritable novel genotype
- Phenotype/visible traits, e.g., color



35 U.S.C. §§ 101 et seq. www.calyxlaw.com

(12) United States Patent Lewis et al.

(10) Patent No.: US 9,095,554 B2

(45) **Date of Patent:** Aug. 4, 2015

(54) BREEDING, PRODUCTION, PROCESSING AND USE OF SPECIALTY CANNABIS



(57) ABSTRACT

The invention provides compositions and methods for the breeding, production, processing and use of specialty *cannabis*.



google.com/patent/US9095554 www.calyxlaw.com

Plant claimed by reference to specific bud characteristics:

The invention claimed is:

- 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 B_T/B_D 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.

- Genotype
- Terpene profile
- Terpene oil content
- CBD content

Having multiple characteristics in combination allowed applicants to demonstrate non-obviousness



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Claimed invention is not simply to a specific plant:

The invention claimed is:

- 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 B_T/B_D 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.

- All plants having the claimed characteristics
- As well as clones, plant parts, tissues, cells

Most important difference compared to a plant patent



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Contains multiple claims beyond just those to plants:

- 10. A method of breeding chemotype II cannabis plants with a non-myrcene dominant terpene profile, said method comprising:
- 11. A method of producing a chemotype II cannabis plant with a non-myrcene dominant terpene profile, said method comprising:
- 12. A cannabis extract from the hybrid cannabis plant, or an asexual clone of said hybrid cannabis plant, or a plant part, tissue, or cell thereof of claim 1.
- 15. An edible product comprising the cannabis extract of claim 12.

- Methods of breeding and producing plants
- Extracts
- Edibles

Many other possible claim types: What are my most important uses? What might competition try to do?



Plant Patent

"Whoever **invents or discovers** and **asexually reproduces** any **distinct and new variety of plant** . . . may obtain a patent therefor."

- Separate specific patent regime for certain asexually reproduced plants
- Easier, faster, and less expensive to secure than a utility patent, but protection is limited



Plant Patent - Basics

- Administered by the USPTO
- ♦ USPTO fees = \$2-3,000; no maintenance fees
- Attorney fees ≅ \$3,500 \$7,500
- ~14 months before application first reviewed
- ~18-24 months before typical application granted
- ~90-95% of applications are eventually granted (significantly higher than rate for utility patents)



Plant Patent - Protection

- 20 years from date of filing
- Right to exclude others from making, using, selling, offering for sale, and importing the plant
- Protection extends only to a single plant itself and its asexually reproduced progeny – thus, one could recreate the variety from a similar set of crosses and defeat patent protection (unlike with a utility patent)
- Cannot claim plant products, uses, methods, etc.



Plant Patent - Requirements

- New: not on sale or publicly described and available more than one year prior to application
- Distinct: must differ from known, related plants by at least one distinguishing characteristic
- Described as completely as reasonably possible
- Must have been <u>invented</u>, or <u>discovered</u> in a cultivated area (not in the wild)
- Must have been successfully <u>asexually reproduced</u>



Example Plant Patent

(12) United States Plant Patent Kubby

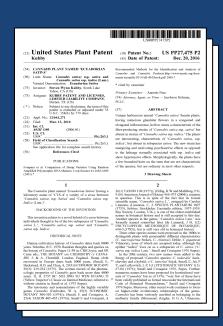
(10) Patent No.:

US PP27,475 P2

(45) Date of Patent:

Dec. 20, 2016

(54) CANNABIS PLANT NAMED 'ECUADORIAN SATIVA'



(57) ABSTRACT

Unique herbaceous annual 'Cannabis sativa' female plants, having numerous glandular flowers in a congested and elongated inflorescence, hollow stems a characteristic of the fiber-producing strains of 'Cannabis sativa ssp. sativa' but absent in strains of 'Cannabis sativa ssp. indica.' The plants are intoxicating, characteristic of 'Cannabis sativa, ssp. indica', but absent in subspecies sativa. The new strain has energizing and motivating psychoactive effects as opposed to the lethargy normally associated with ssp. indica and show hypotensive effects. Morphologically, the plants have a few branched hairs on the stem that are not characteristic of the species, but are ordinary in most other respects.



google.com/patent/USPP27475 www.calyxlaw.com

Example Plant Patent

As with all plant patents, only contains a single claim:

1. A new and distinct cultivar of 'Cannabis' plant, as shown and described.

Hence the protection is limited to that **single specific plant** and its clones



Example Plant Patent

To show that the variety is **distinct**, applicants stated:

- The strain has low levels of Beta Myrcene, Beta Caryophyllene and Linalool
- "Limonene level is extraordinarily high at a level of 4.53, 10 to 20 times the usual range"
- Thus the strain is distinct "from other varieties in its odor, the effects on mood and mentation and its medical qualities"



Example Plant Patent (2)

A recently published application (not yet granted) to:

- A new and distinct cultivar of Cannabis Sativa plant named 'Avidekel'
- Distinct because "characterized by a high amount of Cannabidiol of greater than approximately 16% and a very low amount of THC of less than 1%"



PVPA Certificate

"The breeder of any **sexually reproduced or tuber propagated** plant variety . . . shall be entitled to plant variety protection for the variety . . . if the variety is" **new, distinct, uniform, and stable**.

- PVPA = Plant Variety Protection Act, which provides plant breeder's rights under U.S. international treaty obligations
- Middle-ground protection for relatively low cost and low difficulty – but <u>currently not available for cannabis</u>
- Information on following slides provided for reference



PVPA Certificate – Basics

- Administered by the U.S. Dep't of Agriculture
- \$4,382 application fee; no maintenance fees
- Attorney fees ≅ \$2,500 \$5,000
- * Relatively fast application process



PVPA - Protection

- 20-25 years from date of grant (versus filing)
- Right to exclude others from selling, offering for sale, reproducing, importing, or exporting variety
- For sexually reproduced and tuber propagated plants



PVPA – Requirements

- New: not sold more than one year before filing
- Distinct: "clearly distinguishable from any other variety"
- Uniform: "any variations are describable, predictable, and commercially acceptable"
- Stable: "when reproduced, will remain unchanged with regard to the essential and distinctive characteristics of the variety"



PVPA and Cannabis

- PVPA applicants must make a seed deposit to a USDA facility in Fort Collins, Colorado
- That facility refuses to accept cannabis seeds citing Federal illegality
- Until that changes, PVPA applications for cannabis strains will be returned as incomplete

Accordingly, PVPA protection for cannabis strains is <u>not possible</u> under current law



Comparison of Protection

	Utility Patent	Plant Patent
Term	20 years from filing	20 years from filing
Rights	Right to exclude others from making, using, selling, offering for sale and importing	Right to exclude others from making, using, selling, offering for sale and importing
Plant Protection	All plants having the claimed characteristics	A single plant and its clones
Additional Protection	Yes – plant products, uses, methods, etc.	No – plant only
Cost, speed, and ease of application	Higher cost, longer application pendency, lower likelihood of grant	Lower cost, shorter application pendency, higher likelihood of grant



Is Protection Available?

- Are there **new** strains developed in house and not on sale for over a year?
- Do any of these strains have distinct and nonobvious characteristics?



Is Protection Reasonable?

- Will the claimed strain still be relevant when the patent finally issues?
- Does business case justify expense of patenting?
- Is a plant patent sufficient to capture competing activity, or are broader utility patent claims necessary?



Alternatives to Patenting

- "Open sourcing" strain information by putting it into public domain to prevent strains from being patented
 - E.g., Open Cannabis Project
- Appellations to prevent unfair competition and help ensure strain consistency and quality
 - E.g., Mendocino Appellations Project
- Trademarking strain names
 - May become possible in California in the future (see AB 64)





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