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# PANITCH TRAINING ACADEMY

Insights From Leaders In IP Law

Training Academy Session

# IP Options for Protecting Cannabis Innovations

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# Session Overview

1. Learning the lingo

2. The types of cannabis innovations that can be – and are being – protected using patent rights (e.g., formulations, treatment methods, and the plants themselves)

3. Options for protecting cannabis plant varieties

4. Other types of IP rights that are being applied to the protection of cannabis innovations

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# Learning the Lingo

- Cannabis, cannabinoids, hemp, and marijuana
- Plant species vs. variety/cultivar vs. trade name
- Asexually vs. sexually reproduced

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# Cannabis vs. hemp vs. marijuana

- Cannabis = any plant variety within the species *Cannabis sativa*
  - Could be high- or low-THC
- "Cannabinoids" are a class of unique compounds that cannabis plants produce
  - THC (delta-9-tetrahydrocannabinol) and CBD are two of the most prominent cannabinoids
    - THC is "psychoactive" and CBD is not
  - Numerous other minor cannabinoids exist, as well (e.g., CBG)
  - Delta-8-THC is now the topic of a lot of discussion

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# Cannabis vs. hemp vs. marijuana

- U.S. law distinguishes between “hemp” and “marijuana” based on their cannabinoid content
  - These provisions were in the 2018 Farm Bill
- Hemp: Cannabis that produces 0.3% THC or less is considered “hemp”
  - Hemp is federally legal and states enact regulations that provide for hemp production
- Marijuana: Cannabis that produces >0.3% THC is marijuana
  - Marijuana is still illegal under the CSA
- “THC” in this context is delta-9-THC, not delta-8-THC

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# Species vs. Variety/Cultivar vs. Trade Name

- Species ≠ variety/cultivar ≠ trade name
  - Species is the overall type of plant that it (e.g., *Cannabis sativa*)
  - Plant cultivar, a.k.a. plant variety, is the specific variation of that plant species
    - The official variety denomination is indicated with single quotes (e.g., 'HURV19PAN' cannabis)
  - Trade name is the brand name that the plant is sold under (e.g., Panakeia™ brand hemp)
    - In some cases, it is just sold under the variety name, and in others it is sold under a trademark name

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# Species vs. Variety/Cultivar vs. Trade Name

- You do not get protection over a plant species, you get protection over a plant variety/cultivar
- You cannot get trademark protection over an official variety denomination, but you can protect a variety with a different trademark
- Example:
  - Species = apple (*Malus domestica*)
  - Cultivar/variety = 'Cripps Pink' Apple
  - Trade name = Pink Lady® Apple

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# How is the plant reproduced? It matters!!

- Depending on the type of plant species and variety, plants can be reproduced either sexually or asexually
  - Asexual reproduction = making exact copies or clones of a plant
    - Done through cutting, rooting, grafting, tissue culture, etc.
  - Sexual reproduction = seed reproduction
    - Done by combining pollen and egg to produce a fertilized seed
    - The pollen and egg can be taken from the same plant, two different plants of the same variety, or completely different varieties of plants

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# How do patents apply to cannabis inventions?

- Utility patents can be used to protect novel and inventive compositions and methods
  - This could include compositions and methods that relate to or include cannabis
  - Plant varieties can also be protected using utility patents

- Plant patents are used to protect novel asexually reproduced plant varieties
  - Plants that are only reproduced sexually (by seed) cannot be protected using plant patents
    - Cannabis plants are produced both sexually and asexually, depending on the particular variety

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# How do patents apply to cannabis inventions?

- Patents exist only under federal law, and marijuana is still federally illegal

- *BUT* the legal status of cannabis is irrelevant to patentability
  - There is nothing in the patent laws (35 U.S.C.) that says the legality of the innovation is relevant to patentability
    - Not the same result when talking about trademarks

- Even before hemp was legalized, many cannabis innovations were being submitted in patent applications

- The USPTO has been issuing cannabis utility patents for years!

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# Historic cannabis patents

- The "original" cannabis patent:
  - Patent 6,630,507 (issued Oct. 7, 2003)
    - **Issued to U.S. Dept. of Health and Human Services**

> We claim:
>
> 1. A method of treating diseases caused by oxidative stress, comprising administering a therapeutically effective amount of a cannabinoid that has substantially no binding to the NMDA receptor to a subject who has a disease caused by oxidative stress.

  - This patent has been used to highlight the Schedule I drug hypocrisy!
    - Schedule 1 means it has no currently accepted medical use

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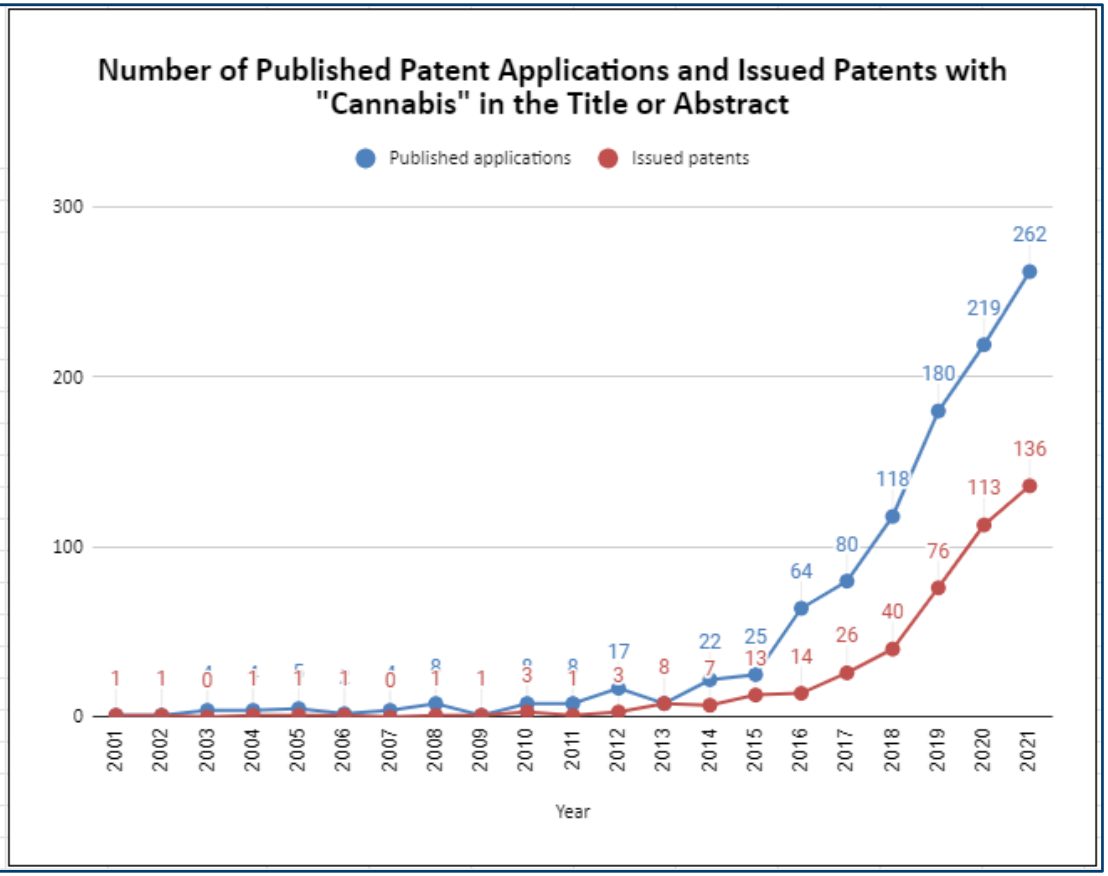
# Historic cannabis patents

- This was not actually the first cannabis patent – patents relating to cannabis have been issuing for decades
  - Example: Patent 4,279,824 issued in 1981 for "Method and apparatus for processing herbaceous plant materials including the plant *cannabis*"

# Cannabis IP is booming!

## Published Patent Applications and Issued Patents with "Cannabis" in the Title or Abstract

| Year | Published applications | Issued patents |
|---|---|---|
| 2001 | 1 | 1 |
| 2002 | 1 | 1 |
| 2003 | 4 | 0 |
| 2004 | 4 | 1 |
| 2005 | 5 | 1 |
| 2006 | 2 | 1 |
| 2007 | 4 | 0 |
| 2008 | 8 | 1 |
| 2009 | 1 | 1 |
| 2010 | 8 | 3 |
| 2011 | 8 | 1 |
| 2012 | 17 | 3 |
| 2013 | 8 | 8 |
| 2014 | 22 | 7 |
| 2015 | 25 | 13 |
| 2016 | 64 | 14 |
| 2017 | 80 | 26 |
| 2018 | 118 | 40 |
| 2019 | 180 | 76 |
| 2020 | 219 | 113 |
| 2021 | 262 | 136 |

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# Cannabis IP rights are enforceable!

- Patents and trademarks are enforced through lawsuits exclusively in federal courts
- Early concern in the industry that federal courts would not enforce cannabis patents because it is not federally legal
- Courts have shown a complete willingness to enforce cannabis patents!

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# Cannabis IP rights are enforceable!

- United Cannabis Corp. ("UCANN") v. Pure Hemp Collective, Inc., 1:18-cv-01922-NYW (D. Colo.)
  - Patent was for a high-THC liquid cannabis formulation
  - The district court handled the case just like any other case
    - Lawsuit eventually was terminated for different reasons

- There are several other cannabis-related litigations that have shown the same thing in different jurisdictions
  - e.g., The Original Resinator, LLC v. TTT Innovations LLC filed in Central District of California in 2021
    - Patent covers cannabis extraction methods
    - Has been treated like any other patent infringement case

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# What types of cannabis innovations are being protected using patents?

- Methods of treatment using cannabis products (e.g., the Dept. of HHS ‘507 Patent)
- Cannabis formulations
- Production methods
- Cannabis plants themselves

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# Patents for Methods of Treatment Using Cannabis

- Patent 9,474,726 for "Use of cannabinoids in treatment of epilepsy" (issued Oct. 25, 2016, to GW Pharma)

> The invention claimed is:
>
> 1. A method of treating treatment-resistant epilepsy comprising administering cannabidiol (CBD) to a subject, wherein the epilepsy is febrile infection related epilepsy syndrome (FIRES).

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# Patents for Methods of Treatment Using Cannabis

- Patent 11,390,437 for "Pharmaceutical formulation" (issued July 19, 2022, to GW Pharma)

> **1**. A method of treating spasms associated with multiple sclerosis in a patient in need thereof, wherein the method comprises administering to the patient a liquid pharmaceutical formulation comprising tetrahydrocannabinol (THC) and cannabidiol (CBD), wherein the liquid pharmaceutical formulation comprises in a 1 mL volume: 22.5-27.5 mg/mL of THC based on amount of cannabinoid in a botanical drug substance, and 22.5-27.5 mg/mL of CBD based on amount of cannabinoid in a botanical drug substance, and wherein the liquid pharmaceutical formulation lacks a self-emulsifying agent.

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# Patents for Cannabis Formulations

- Patent 11,291,631 for "Oral cannabinoid formulations" (issued Apr. 5, 2022, to GW Pharma)

> 1. A pharmaceutical formulation for oral administration comprising:
>
> cannabidiol (CBD);
>
> a lipid solvent;
>
> an ultrahigh potency sweetener; and
>
> ethanol, wherein ethanol has a concentration of less than about 3% v/v.

# Patents for Cannabis Formulations

- Patent 11,426,362 for “Oral cannabinoid formulations” (issued Aug. 30, 2022, to GW Pharma)

> **1**. An oral formulation comprising:
> (i) a plurality of micelles, wherein each micelle comprises a non-ionic surfactant and one or more cannabinoids, wherein the one or more cannabinoids are incorporated within the micelle; and
> (ii) an aqueous solvent comprising water and an antioxidant that is soluble in the aqueous solvent;
> wherein the micelles are miscible in the aqueous solvent.

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# Patents for Cannabis Growing Methods

- Patent 9,538,733 (issued Aug. 4, 2015) "Sustainable Aquaponic System and Method for Growing Plants Like Medical Cannabis"

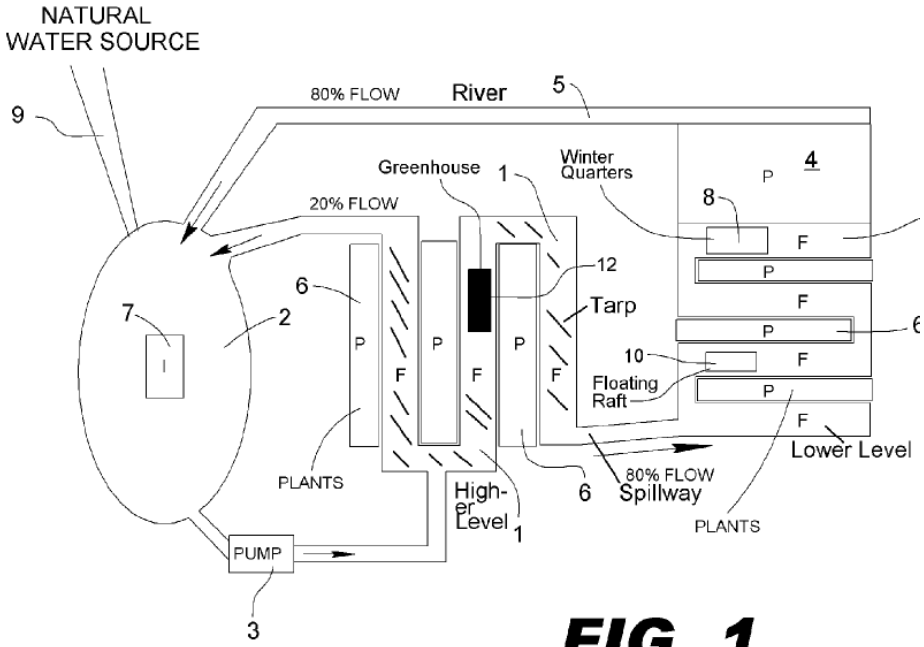


FIG. 1

I claim:

1. A sustainable aquaponics system comprising:

a man-made pond connected by a pump to a plurality of man-made raceways, each raceway lined with tarp and containing a variety of plant species including blue algae placed in the raceway to remove waste materials from raceway water and provide food for fish, wherein each raceway spills water through a man-made spill-way into an adjacent raceway at a lower vertical level;

a source of water from a natural ecosystem feeding into said man-made pond;

at least one insulated and heated winter quarters for fish in colder temperatures;

a poly-culture fish population wherein chosen predator fish eat other chosen fish in the system in a food chain wherein lower members in the food chain spawn faster than they are consumed by predator fish higher in said food chain;

wherein said system includes monitoring equipment adapted to ascertain that water contains at least 8.3 ppm of dissolved oxygen;

a plurality of man-made plant growing areas adjacent to or on said raceways, at least some of said plant growing

# Patents for Cannabis Growing Methods

- "Automated lighting system for uniform growth of medical cannabis"
  - Filed Jun. 4, 2015; published Dec. 8, 2016
- "Methods and systems of cultivation"
  - Filed May 18, 2016; published Nov. 24, 2016
- "Methods of cannabis cultivation using a capillary mat"
  - Filed Sept. 30, 2015; published Mar. 31, 2016

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# Takeaways

- The USPTO treats cannabis patents just like all others
  - No special hoops to jump through
- Consider all aspects of a cannabis business's operations for possible patentable innovations
- As the field continues to mature and more published information becomes available, patent claims are narrowing

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# Three primary types of varietal IP protection

- Plant Patent
  - Issued by USPTO
- Utility Patent
  - Issued by USPTO
- Plant Variety Protection (PVP) Certificate
  - Issued by USDA

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# Plant Patents: Basics

- Only available for asexually reproduced varieties
- Requires a detailed botanical description, but no data from comparative field trials
- No biological deposit requirement
- Usually takes 3-12 months to get allowed
- Very high allowance rate
- Typical all-in cost is $3K-$8K (no maintenance fees or deposit fees)

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# Plant Patents: Scope of protection

- Gives you the right to exclude others from asexually reproducing the variety and from making, using, or selling those asexually reproduced plants in the U.S. (including whole plants and parts)
- Does not give any protection over:
  - breeding with your new variety
  - using the variety to produce F1 seed
  - essentially derived varieties

# "Varietal" Utility Patents: Basics

- Available for asexually and seed reproduced varieties
- Requires a detailed botanical description, plus sufficient information to support claims relating to breeding, hybrids, mutants, genetic engineering, etc.
- Generally required to make a biological deposit
- Usually takes 12-36 months to get allowed
- Lower allowance rate; depends on claim scope
- Typical cost of $5K-$15K through issuance plus cost of deposit; $7K-$14K in maintenance fees over patent life

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# "Varietal" Utility Patents: Scope of protection

- Gives you the right to exclude others from making, using, or selling your claimed invention
- Scope of the claims dictates scope of protection
- Should provide at least the same scope as a Plant Patent, plus often get protection over:
  - breeding with your new variety
  - using the variety to produce F1 seed
  - essentially derived varieties (mutants, GM versions, etc.)
  - marker hunting in the variety

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# PVPs: Basics

- Available for asexually and sexually reproduced varieties
- Application must include:
  - Detailed botanical description
  - Breeding history and selection process
  - Data from comparative field trials for DUS testing
    - No gov't oversight – just do the trial and report the data
- Must make a seed deposit; no requirement for a tissue culture deposit for clonal varieties until further notice from USDA

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# PVPs: Basics

- Usually takes 6-18 months to get allowed
- Very high allowance rate
- Typical all-in cost is $6K-$10K total for application, plus cost of deposit ($3K-$4K for TC - not required at this time)
    - No downstream maintenance fees

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# PVPs: Scope of protection

- Gives you the right to exclude others from making, using, or selling your particular cultivar in the U.S.
- Also protects:
  - using the variety to produce F1 seed
  - essentially derived varieties
- No protection over breeding with the variety

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# How IP options apply to cannabis cultivars

- U.S. law distinguishes between “hemp” and “marijuana”

| Hemp | Marijuana |
|---|---|
| 0.3% THC or less | >0.3% THC |
| Federally legal | Illegal under the CSA |

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# How IP options apply to cannabis cultivars

- Plant Patents:
  - Can be used for any cannabis variety regardless of THC content that is reproduced asexually
- Utility Patents:
  - Can be used for asexual and seed reproduced varieties
  - Requires a biological deposit, which may be difficult for marijuana
- PVPs:
  - Can be used for asexual and seed reproduced varieties
  - Only allowed for hemp, not marijuana

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# Comparison of the three types of protection

| | Plant Patent | PVP | "Varietal" Utility |
|---|---|---|---|
| **Eligible cannabis** | Hemp or marijuana | Hemp only | Hemp =yes; marijuana = yes, if you can deposit |
| **Type of reproduction** | Asexual only | Both seed and asexual | Both seed and asexual |
| **Deposit req't** | No | Yes for Seed<br>Not now for TC | Yes |
| **Scope of protection** | Only specific cultivar developed | Specific cultivar + hybrid seed produced for sale + essentially derived varieties | Specific cultivar + hybrids, mutants, breeding, marker identification, etc. |
| **Disclosure required** | Botanical description and distinguish from other varieties | Breeding history, botanical description, distinct, uniform, stable | Plant Patent description + additional support for the broader claims |
| **Time bar for filing** | 1 year from sale, on sale, or public availability anywhere in world | 1 yr from U.S. sale; 4/6 yrs from sale elsewhere | 1 year from sale, on sale or public availability anywhere in world |
| **Duration** | 20 years from filing | 20 years from *issuance* | 20 years from filing |
| **Approx. cost** | $3K-$8K total | $6K-$10K total | $5K-$15K through issuance (plus cost of deposit and $7K-$14K in maintenance fees) |

# Overall Trends in IP Protection for Cannabis Cultivars

- Plant Patents are becoming more common
- PVPs are just starting to take off
- Utility Patents for cannabis have been expanding for many years
    - Claim scope differs greatly

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# Plant Patents are rapidly expanding

## Plant Patents for Cannabis Varieties

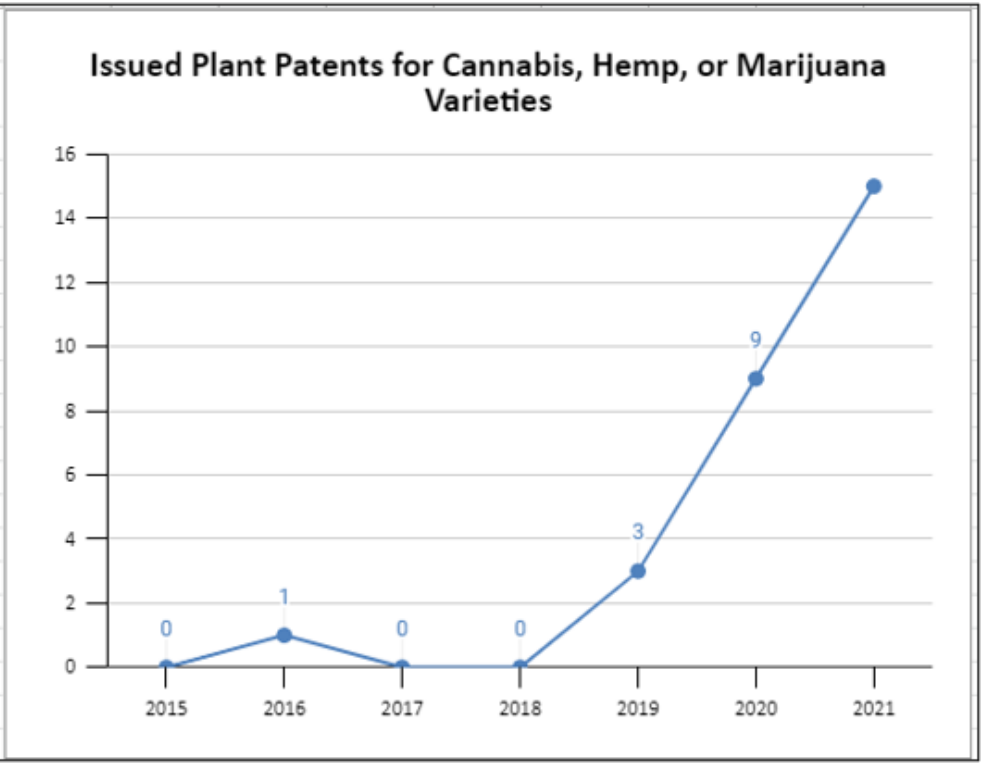
| Year | Issued Plant Patents | Hemp | Marijuana |
|---|---|---|---|
| 2015 | 0 | 0 | 0 |
| 2016 | 1 | 0 | 1 |
| 2017 | 0 | 0 | 0 |
| 2018 | 0 | 0 | 0 |
| 2019 | 3 | 1 | 2 |
| 2020 | 9 | 0 | 9 |
| 2021 | 15 | 6 | 9 |

**Primary distinguishing features:**

Chemotype (High CBG, high CBDA, high THCV, terpene blend)
Fungal disease resistance
High flower and trichome yield
Microbial resistance (Aurora)
Reduced intra-flower leaves (Aurora)
Hemp-hops hybrid
Reduced leaf chlorophyll

**Most patents held:**

Biotech Institute

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# PVPs are just starting to take off

- USDA granted a few PVPs for hemp back in 2014 then decided they would not allow cannabis to be protected
- Following passage of 2018 Farm Bill, USDA said that it would allow PVP protection for hemp varieties (but not marijuana)
- Now PVPs for hemp are starting to take off
- The first clonally propagated variety was issued a PVP certificate in 2020

**Issued PVP Certificates for Novel Hemp Varieties**

| Year | PVP Applications | Issued PVP Certificates |
|---|---|---|
| 2010 | 1 | 0 |
| 2011 | 2 | 0 |
| 2012 | 0 | 0 |
| 2013 | 0 | 0 |
| 2014 | 0 | 2 |
| 2015 | 0 | 0 |
| 2016 | 0 | 0 |
| 2017 | 0 | 0 |
| 2018 | 0 | 0 |
| 2019 | 4 | 0 |
| 2020 | 6 | 5 |
| 2021 | 2 | 8 |

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# Recent Utility Patents for Cannabis Plants:

- There is a similar expansion of utility patents directed toward cannabis varieties
- Recent examples:
  - Charlotte's Web Inc. utility patents for several seed-reproduced hemp varieties (‘CW1AS1’, LINDOREA’, and ‘KIRSCHE’)
  - Tweed Inc. patent for "Cannabis plants having modified expression of THCA synthase"

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# Charlotte's Web Patents

- 4 recent patents covering 3 seed-reproduced hemp varieties
  - 'CW1AS1' (US 10,653,085 and 10,736,295), 'LINDOREA' (US 10,888,059), and 'KIRSCHE' (US 10,888,060)
- 'CW1AS1' (the first application) relied on a deposit made in Scotland (like Biotech Institute); later patents relied on a deposit made at Bigelow lab in Maine
- All varieties have essentially the same coverage / claim scope

# Charlotte's Web Patents

- Seed, plant, or plant part of the variety (as deposited)
- Plant having all of the physiological and morphological characteristics of the variety (as described in the patent)
- Plant having a single gene change from or transgene insertion into the variety
- Method of producing a derived cannabis plant by doing any of the following with the variety: crossing the variety with another variety, mutation breeding, using marker assisted selection, pedigree breeding, backcrossing, open-pollination, hybridization, mass selection, recurrent selection

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# Charlotte's Web Patents

- Also covers:
  - further crosses of the derived cannabis plant with itself or another variety
  - extracting or vaporizing the derived plant
  - isolating nucleic acids from the variety
  - producing a commodity plant product or extract by harvesting material or extracting material from their varieties

# Tweed Inc. Patent

- U.S. Patent No. 10,934,554 for "Cannabis plants having modified expression of THCA synthase"
- They describe and claim use of antisense RNA, siRNA, and CRISPR
  - Antisense RNA and siRNA generally makes the plant GMO in the U.S.
  - CRISPR is generally not genetically modified in the U.S. so long as the CRISPR machinery is delivered as RNPs

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# Tweed Inc. Patent

- No particular varieties are claimed, just the method of genetically modifying the plant and plants and seeds made by that method
- They also claim medical cannabis compositions prepared using plants prepared by the method
- No deposit because they never actually developed any varieties

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# Use of other IP rights to protect cannabis innovations

- Trademarks
- Trade secrets
- Licensing cannabis IP rights

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# Trademark Protection

- Primary sources of trademark protection in the U.S.
  - Common law trademark protection
    - Based solely upon use
    - Geographically limited
  - State trademark registration
  - Federal trademark registration
    - Presumption of nationwide priority
    - Other benefits

# Federal Registration

- Unique Requirements that Impact Federal Trademark Protection for Cannabis Marks
  - Unlike other forms of IP, U.S. federal trademark law requires:
    - Use of a mark in commerce must be lawful under federal law to be the basis for federal registration under the U.S. Trademark Act
    - The USPTO also requires proof of lawful use prior to issuance of a registration
- As a result, the USPTO refuses to register marks for goods and/or services that show a clear violation of federal law, regardless of the legality of the activities under state law
  - Historically that included all cannabis products

# Federal Registration

- 2018 Farm Bill legalized hemp
- In May of 2019, the USPTO issued a new examination guide for cannabis products.
- It indicated that the USPTO looks to several different federal laws to determine whether the goods/services sought to be registered are lawful under federal law.
- These include:
  - Controlled Substances Act
  - Federal Food Drug and Cosmetic Act
  - 2018 Farm Bill (the Agriculture Improvement Act)

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# Federal Registration

- CSA
  - The CSA prohibits, among other things, manufacturing, distributing, dispensing, or possessing certain controlled substances, including marijuana. 21 U.S.C. §§812, 841(a)(1), 844(a).
    - Farm Bill excluded "hemp" from the definition of marijuana
  - Therefore, the USPTO now refuses TM registration when an application identifies goods encompassing >0.3% THC (i.e., non-hemp cannabis) because such goods are unlawful under federal law and do not support valid use of the applied-for mark in commerce

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# Federal Registration

- FDA
  - Even if the goods are considered “lawful” under the Farm Bill, there could still be potential concerns under the FDCA
    - The use in foods or dietary supplements of a drug or substance undergoing clinical investigations without approval of the U.S. Food and Drug Administration (FDA) violates the
    - The 2018 Farm Bill explicitly preserved FDA’s authority to regulate products containing cannabis or cannabis-derived compounds under the FDCA.
  - As a result, the USPTO will still refuse registration of marks for foods, beverages, dietary supplements, or pet treats containing CBD that have not been approved by FDA, even if derived from hemp

# Protection for Ancillary Products

- At the federal level, another possibility is to seek trademark protection for ancillary products – clothing, publications, informational websites
- In practice, however, the USPTO has still been relatively strict on allowing registration for products that it believes may be used in relation with cannabis or cannabis-related products

# Alternative Routes of Brand Protection

- State-based trademark registration is a viable alternative to the above hurdles for federal trademark registration
  - Registration of cannabis-related trademarks is allowed in all states where cannabis is legal recreationally, and in most states where medical use is permitted.
  - Subject to geographic limitations

# Trade Secrets

- Trade secrets exist at both the state and federal level
  - Most states have trade secret laws that follow the Uniform Trade Secrets Act
  - Federal Defend Trade Secrets Act ("DTSA") was enacted in 2016 to give a federal cause of action for trade secret misappropriation – 18 U.S.C. § 1836 et seq.

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# Trade Secrets

- A trade secret can be any information that derives independent economic value from not being generally known to, and not being readily ascertainable by proper means by, other persons who can obtain economic value from its disclosure or use

- Must take reasonable steps to protect the secrecy of the information, such as:
  - Limiting access within the company
  - Using confidentiality agreements

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# Trade Secrets

- DTSA can be used to protect cannabis-related trade secrets
  - State trade secret law can, as well
- Federal courts have shown a willingness to enforce the DTSA for cannabis-related inventions
  - Silva Enters. v. Ott, 2018 U.S. Dist. LEXIS 223854, *13 (C.D. Cal. 2018)
  - Defendant argued “that plaintiffs have not stated a claim for misappropriation of trade secrets because ‘there is no trade secret protection for ongoing illegal activities.’”
  - District court rejected that argument, holding that the CSA, which makes cannabis illegal, “does not immunize defendants from federal [trade secret] law.”

# Trade Secrets

- Businesses must choose between trade secret protection and patent protection for a particular innovation
  - But could combine patent protection on a composition and trade secret covering the method of making the composition

- Decision depends on numerous factors including:
  - Method vs. composition
  - Internal vs. external
  - Difficulty for a competitor to independently develop the trade secret info
  - Useful life of the information

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# Licensing IP assets

- Securing IP protection is just the beginning, not the end goal
- IP rights give you the right to exclude others from selling your protected invention and/or using your brand name
  - Can use that to just maintain a monopoly so that you are the only seller of that variety/brand
  - Can license your rights to others to expand your reach and generate an income stream not limited by your ability to grow plants
- Licenses can create an additional layer of pseudo-IP protection

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# Licensing IP assets

- Licenses often include multiple types of IP rights
  - Patent + trademark
  - Patent + trade secret / know how
- Licenses are based on state contract laws, not federal law
- States where cannabis is legal have shown complete willingness to treat cannabis contract disputes like any other contract dispute

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# Licensing cannabis varieties

- Licensing cannabis varieties/genetics is increasingly common
- License schemes for cannabis varieties can be quite complex
- Create a revenue stream for variety owners that is not tied to the size of their own grow

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# Primary license considerations

- What are your licensees doing for you?
  - Propagating plants? Generating seed? Selling flower?
  - Exclusive or nonexclusive? Exclusive in a particular territory?
- Need to think through the entire license scheme on the front end to make sure the proper licenses are in place




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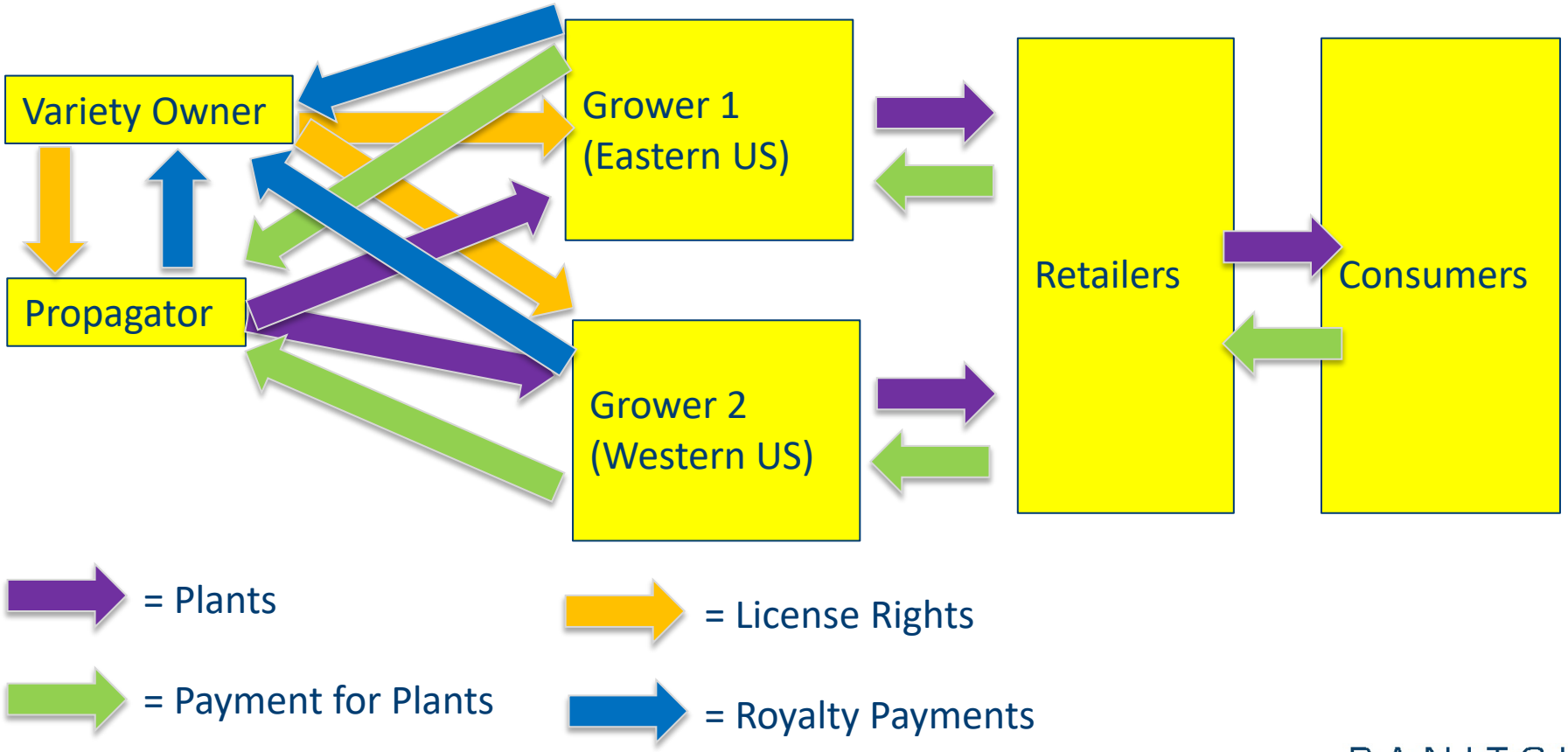
# Example license scheme

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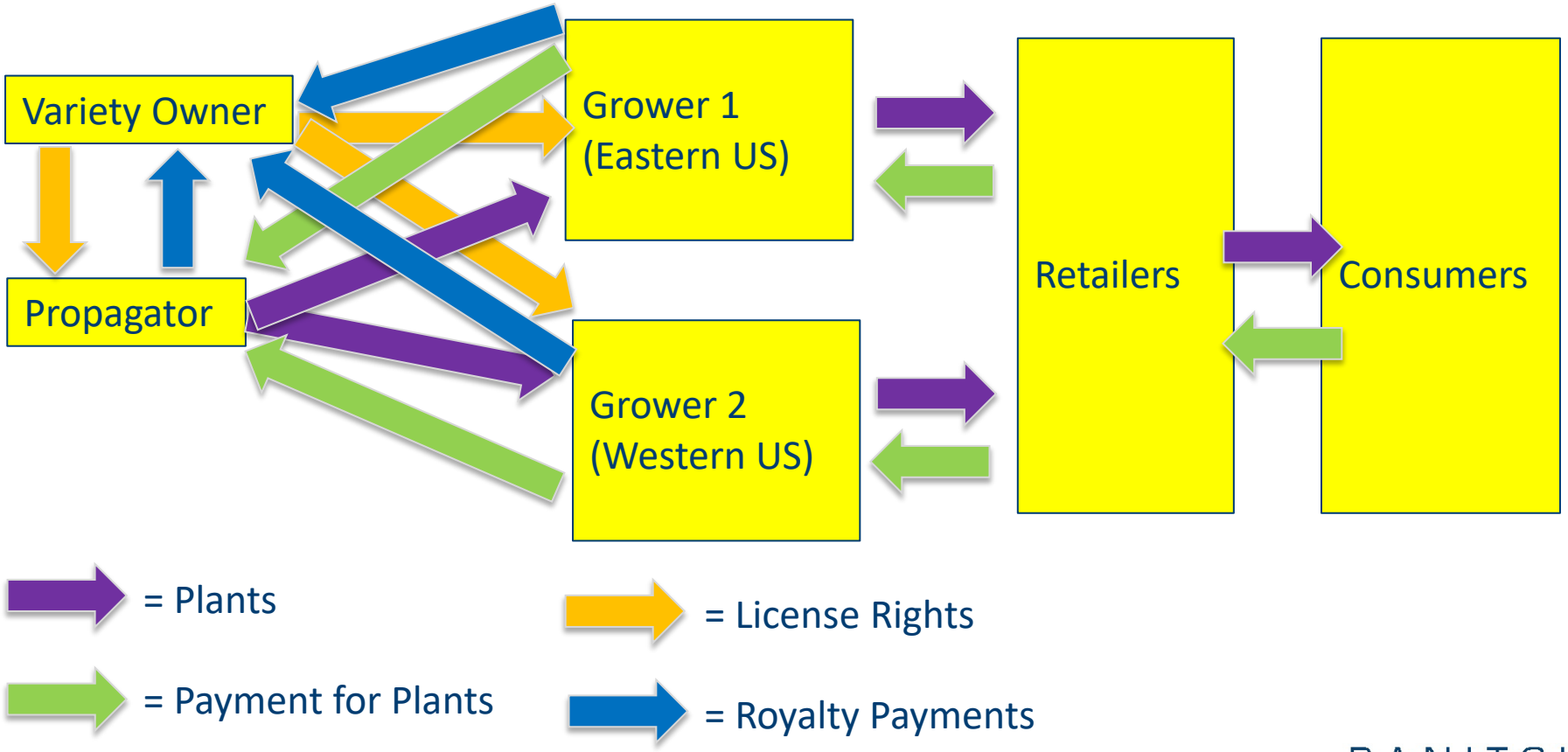
# Example license scheme

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# Takeaways

- Cannabis innovations can be protected under both state and federal law
  - There are some caveats and difficulties for certain products, but there are generally ways that good protection can be secured if you have a good plan
- Courts have been willing to enforce cannabis IP rights just like they would for any other industry
- Look at all pieces of a cannabis business to determine what types of IP protections should be used
  - Think of IP up front, not as an afterthought, so that the appropriate protections can be obtained and combined to help drive revenue

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# Speakers

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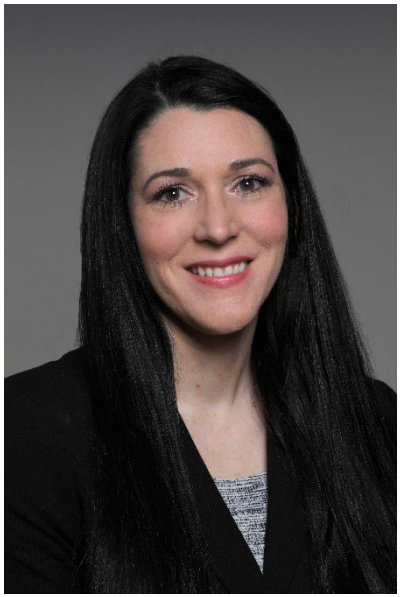

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