



Training Academy Session #7

# IP Rights and Issues for Cannabis Plants

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## Session Overview

- Learning the lingo (Travis)
- The three U.S. IP options for protecting a new plant variety (Stephany)
- Overall Trends in IP Protection for Cannabis Cultivars (Travis)
- Trademarks for new plants varieties (Steve)
- How trademarks apply in the realm of cannabis varieties (Steve)
- Combining multiple types of protection to build a stronger IP fence (Travis)
- Monetizing your IP rights through licensing strategies (Travis)

## Learning the Lingo

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

## Species vs. Variety/Cultivar vs. Trade Name

- Species ≠ cultivar/variety ≠ 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

## Species vs. Variety/Cultivar vs. Trade Name

- You do not get protection over a plant species, you get protection over a plant cultivar/variety
- 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

## 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

## Cannabis vs. hemp vs. marijuana

- Cannabis = any plant variety within the species *Cannabis sativa*
  - Could be high- or low-THC
- U.S. law distinguishes between “hemp” and “marijuana”
- Provisions were in the 2018 Farm Bill (which also added PVP protection for asexually reproduced varieties)
- 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

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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

## 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 4-12 months to get allowed
- Very high allowance rate
- Typical all-in cost is \$3K-\$8K (no maintenance fees or deposit fees)

## 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

## Plant Patents: Novelty bar

- Sale, offer for sale, or public availability of the variety anywhere in the world >1 year prior to filing will destroy novelty
- But prior disclosure >1 year before the patent app is filed will likely not destroy novelty as long as the plant was not publicly available
  - A description of the plant is not enabling because someone cannot create the exact same plant variety without having access to the variety

## “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

## “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

## “Varietal” Utility Patents: Novelty bar

- Same novelty bar as a Plant Patent
  - No sales, offers for sale, or public availability anywhere in the world >1 year prior to filing the application
  - Just a disclosure of the variety should not destroy novelty

## 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; starting in 2023 must make a TC deposit for clonal varieties



## 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)
  - No downstream maintenance fees

## 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

## PVPs: Novelty bar

- Novelty bar is dependent on where the sale occurred:
  - Sales within the U.S. >1 year before application date destroy novelty
  - Sales outside the U.S. >4 years before the application date destroy novelty

## 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

## 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

## Comparison of the three types of protection

	Plant Patent	PVP	“Varietal” Utility
<b>Eligible cannabis</b>	Hemp or marijuana	Hemp only	Hemp =yes; marijuana = yes, if you can deposit
<b>Type of reproduction</b>	Asexual only	Both seed and asexual	Both seed and asexual
<b>Deposit req’t</b>	No	Yes (asexual delayed until 2023)	Yes
<b>Scope of protection</b>	Only specific cultivar developed	Specific cultivar + hybrid seed produced for sale + essentially derived varieties	Specific cultivar + hybrids, mutants, breeding, marker identification, etc.
<b>Disclosure required</b>	Botanical description and distinguish from other varieties	Breeding history, botanical description, distinct, uniform, stable	Plant Patent description + additional support for the broader claims
<b>Time bar for filing</b>	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
<b>Duration</b>	20 years from filing	20 years from <u>issuance</u>	20 years from filing
<b>Approx. cost</b>	\$3K-\$8K total	\$6K-\$10K total (plus cost of deposit [~\$3K-\$4K for TC])	\$5K-\$15K through issuance (plus cost of deposit and \$7K-\$14K in maintenance fees)

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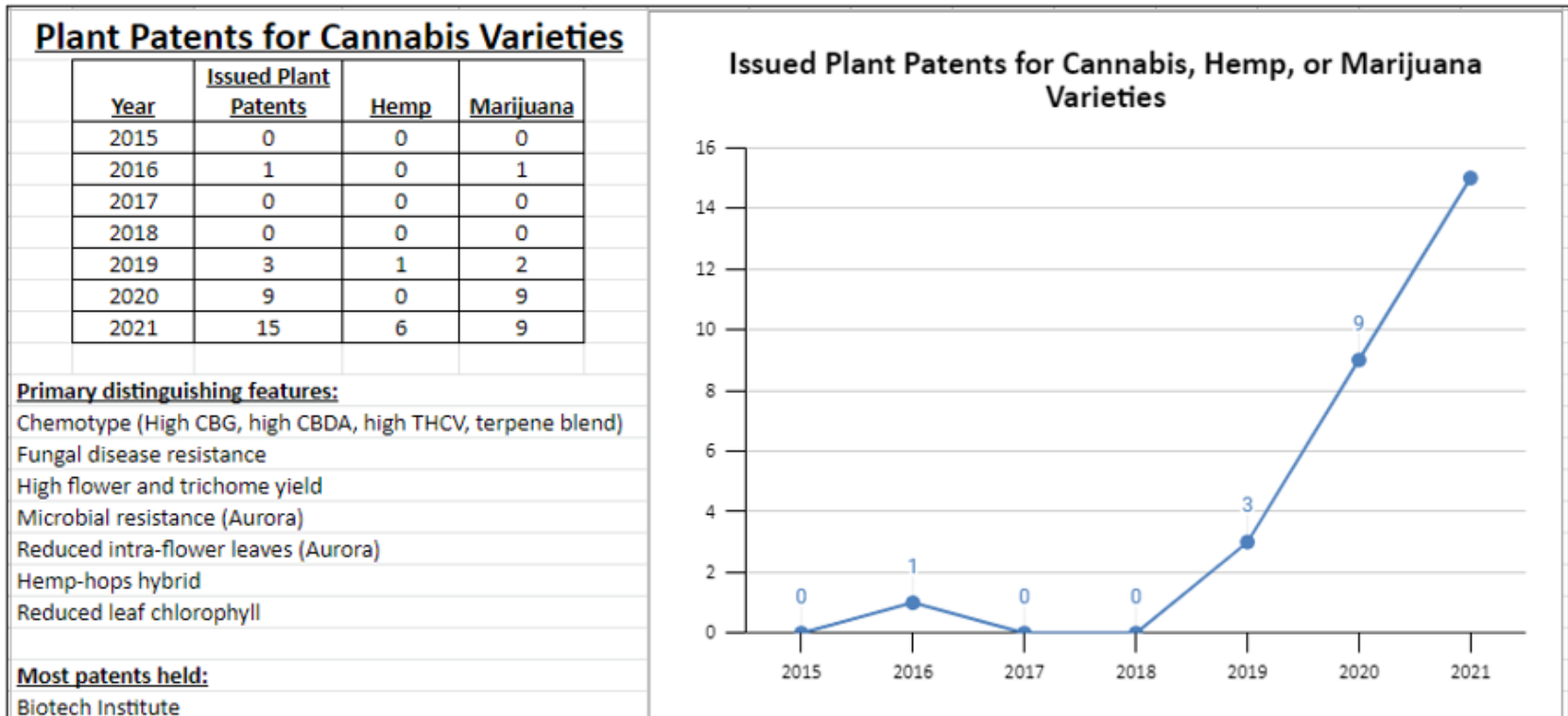
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# Overall Trends in IP Protection for Cannabis Cultivars

- **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



# Plant Patents are rapidly expanding



## PVPs are just starting to take off

- USDA granted a few PVPs for hemp back in 2011 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 happen
- Only one clonally propagated variety has been issued a PVP certificate

<u>Year</u>	<u>Issued PVPs</u>	<u>Seed</u>	<u>Clonal</u>
2010	0	0	0
2011	2	2	0
2012	0	0	0
2013	0	0	0
2014	0	0	0
2015	0	0	0
2016	0	0	0
2017	0	0	0
2018	0	0	0
2019	3	3	0
2020	3	2	1
2021	0	0	0

## Utility Patents:

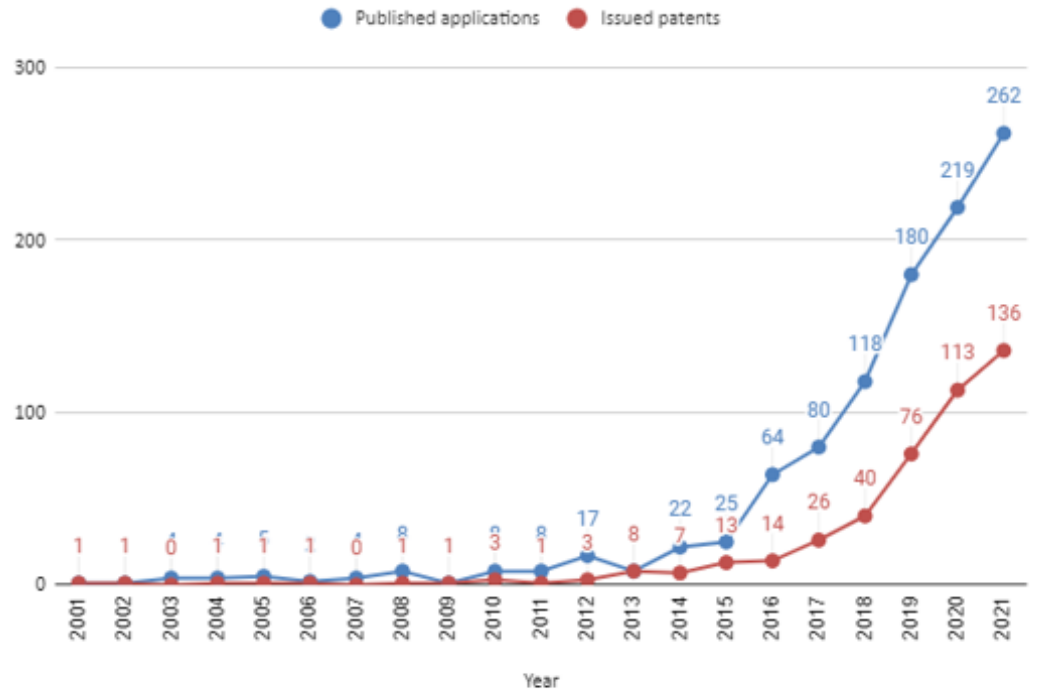
- Utility Patents:
  - Utility patents for cannabis have been expanding for many years
  - Issue rate is good for cannabis innovations
  - Utility patents for cannabis varieties are becoming more common
  - Claim scope varies

# Utility patents are 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

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



## Recent Utility Patents for Cannabis Plants:

- Charlotte's Web Inc. utility patents for several seed-reproduced hemp varieties ('CW1AS1', LINDOREA', and 'KIRSCHE')
- New West Genetics patent for seed-reproduced hemp varieties 'NWG331' and 'NWG452'
- Biotech Institute LLC utility patent for 'YEL03xTP05, an asexually reproduced marijuana variety
- Tweed Inc. patent for "Cannabis plants having modified expression of THCA synthase"

## 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

## 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



## New West Genetics Patent

- U.S. Patent No. 10,499,584 for varieties ‘NWG331’ and ‘NWG452’
  - They protected 2 seed-reproduced hemp varieties in a single patent
- Made a deposit to the same lab in Scotland as Biotech Institute and Charlotte’s Web
- Claim scope similar to Charlotte’s Web

## New West Genetics Patent

- 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)
- Method of producing an F1 hybrid by crossing the variety with a different variety
- Method of producing a derived cannabis plant with <0.2% THC by doing any of the following with the variety: mutation breeding, using marker assisted selection, pedigree breeding, backcrossing, recurrent selection, or genetic modification

## New West Genetics Patent

- Producing a genetically modified version of the variety by transforming the variety with a nucleic acid that confers male sterility, herbicide resistance, insect resistance, disease resistance, or any value-added trait
- Method of introducing a desired trait into the varieties by crossing the variety with another variety that has the desired trait, selecting a progeny, and backcrossing >3 times
- Also covers:
  - beverage prepared from the variety
  - isolates prepared from the variety

## Biotech Institute Patent

- U.S. Patent No. 10,582,676 for variety 'YEL03xTP05'
- This is an asexually reproduced high terpene variety which produces 0.7% THC and 6.2% THCA, so it is marijuana
- They made a TC deposit at the Bigelow lab in Maine – first high-THC variety I have seen deposited there
- Claim scope mirrors what they have gotten in other patents
  - Their other patents are mostly directed toward seed-reproduced varieties, though

## Biotech Institute Patent

- The plant or plant parts (including TC) of the variety with the given terpene and cannabinoid profile
- Method of producing an F1 hybrid by crossing the variety with a different variety
- Also covers:
  - Edible product produced from the variety

## 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

## 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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## Trademarks for new plant varieties

- USPTO treats varietal names as generic
  - Varietal or cultivar names are designations given to cultivated varieties or subspecies of live plants or agricultural seeds.
  - They amount to the generic name of the plant or seed by which such variety is known to the U.S. consumer.
  - Thus, even if the varietal or cultivar name was originally arbitrary, it now describes to the public a plant of a particular sort, not a plant from a particular source.
  - So, an arbitrary name can become the generic name for a plant variety, even if it was intended as a trademark.
  - Refusals can arise based upon genericness.
  - Alphanumeric name vs. Arbitrary trademark

# Trademarks for new plant varieties

- Clearance Searches
  - Not enough to search for similar trademarks
  - Attractive name can be blocked if it is the same as a variety denomination
  - Search of plants certified under the Plant Variety Protection Act listed at <https://www.ams.usda.gov/datasets/plant-variety>
- What to do when someone uses your TM as a variety name
  - Danger of genericization to your TM
  - Check the species/genus to make sure it's different
  - Send letter to other party

## Trademark issues in the realm of cannabis

- Use of a mark in commerce must be lawful under federal law to be the basis for federal registration
- No TMs for marijuana or THC products
  - Controlled Substances Act (CSA)
- TM's OK for hemp under 2018 Farm Bill
  - ...with a delta-9 tetrahydrocannabinol [THC] concentration of not more than 0.3 percent on a dry weight basis.
- CBD products can be OK if FDA approval
  - Federal Food Drug and Cosmetic Act
- State Applications and Registrations

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## Protections are not mutually exclusive!

- You do not necessarily need to choose only one type of protection to obtain
  - You can get more than one of these types of protection to protect the same variety
  - May not want to get all of the protections, but for more valuable varieties, you may want to stack your protections to increase the scope of protection you have

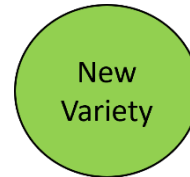
## Strategies for combining multiple types of protection

- File a **U.S. Plant Patent** app to secure baseline protection for your new variety
  - USPP has lowest cost of all three options
  - USPP has highest issuance rate of all three options
  - USPP has fastest allowance of all three options
- For less valuable varieties, this may be all you need!

## Strategies for combining multiple types of protection

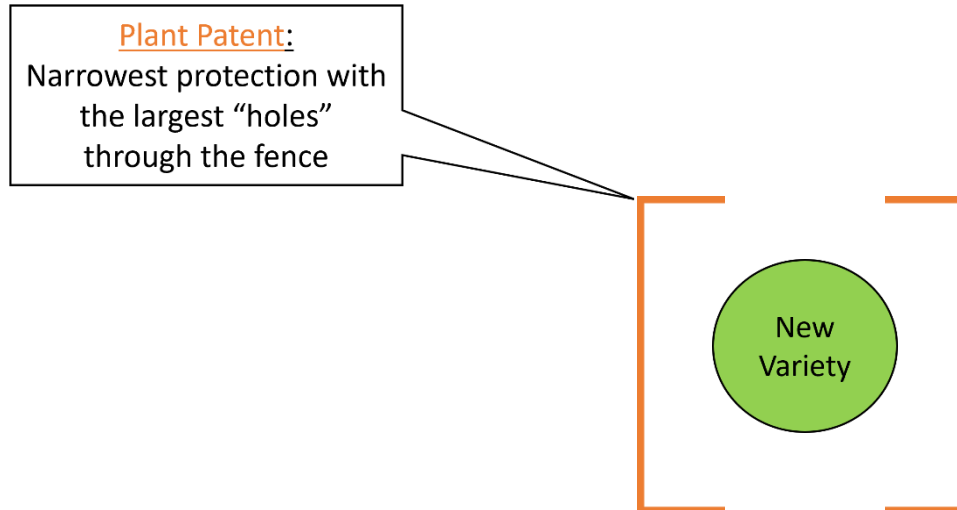
- For more valuable varieties, also file a “Varietal” Utility Patent app or PVP app
  - PVP provides good protection for F1 hybrids and EDV, but not breeding
  - A utility patent is more costly, but it provides the broadest coverage, so this is the way to go for the most valuable varieties you develop
  - Think of it in terms of multiple layers of IP fencing around your invention!

# Strategies for combining multiple types of protection

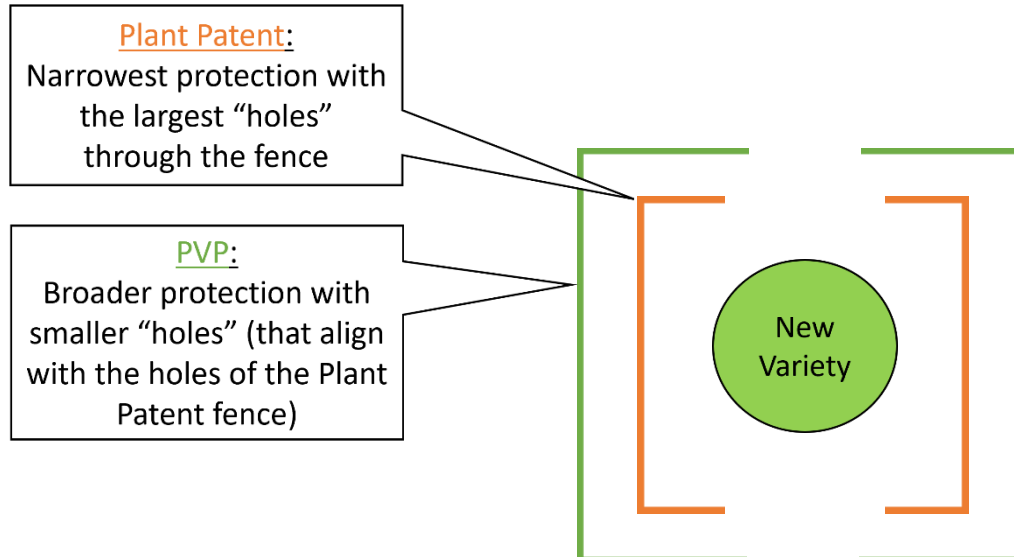




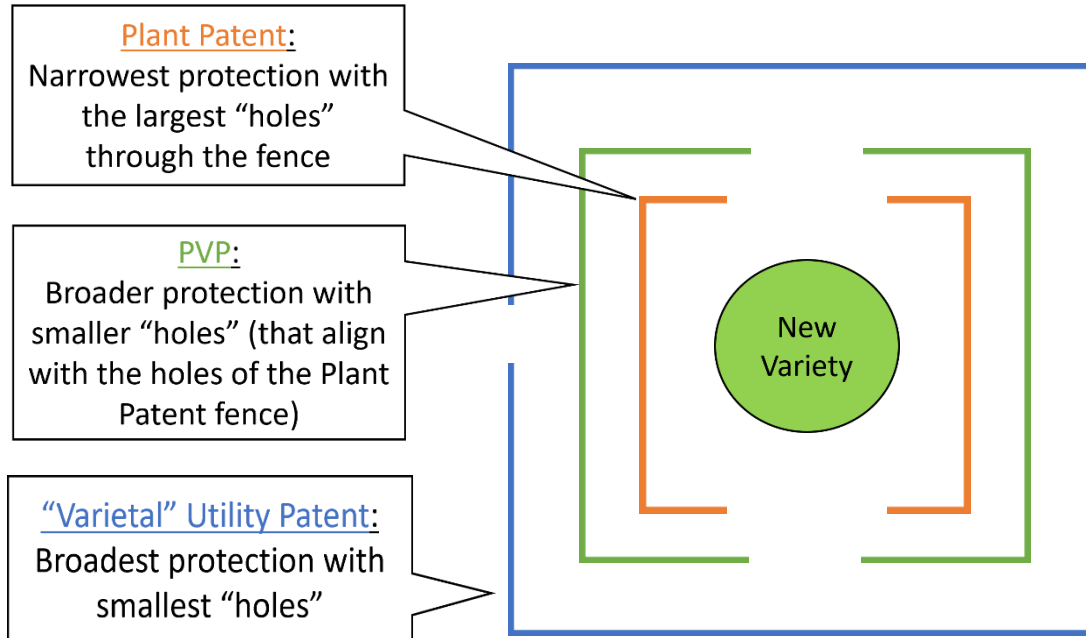
# Strategies for combining multiple types of protection



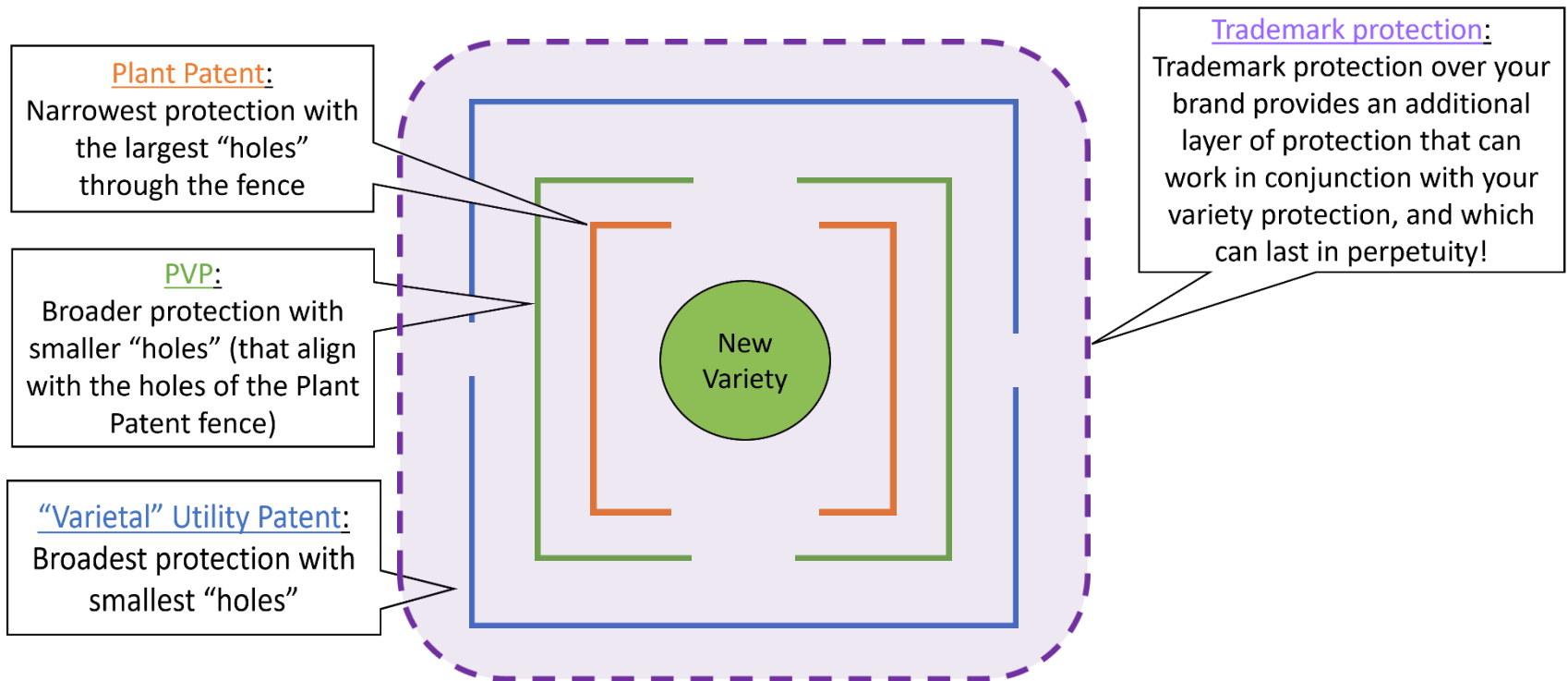
# Strategies for combining multiple types of protection



# Strategies for combining multiple types of protection



# Strategies for combining multiple types of protection



## The bottom line...

- When you develop a new cultivar you should consider what types of IP protection are appropriate right up front
  - You want to get the most appropriate type of protection for your cultivar, which may vary depending on how distinct the new cultivar is and how valuable you believe it will be
- There are time bars that exist, so pursue protection sooner rather than later
- By capturing IP a breeder can stop others from selling a new cultivar without their permission
- But by licensing that IP a breeder can create a new income stream that goes beyond the number of plants they can produce as a grower
- **The ultimate goal is always to ensure a breeder is being properly rewarded for the effort they put into developing a new cultivar!**

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- **Monetizing your IP rights through licensing strategies (Travis)**

## Monetizing IP assets

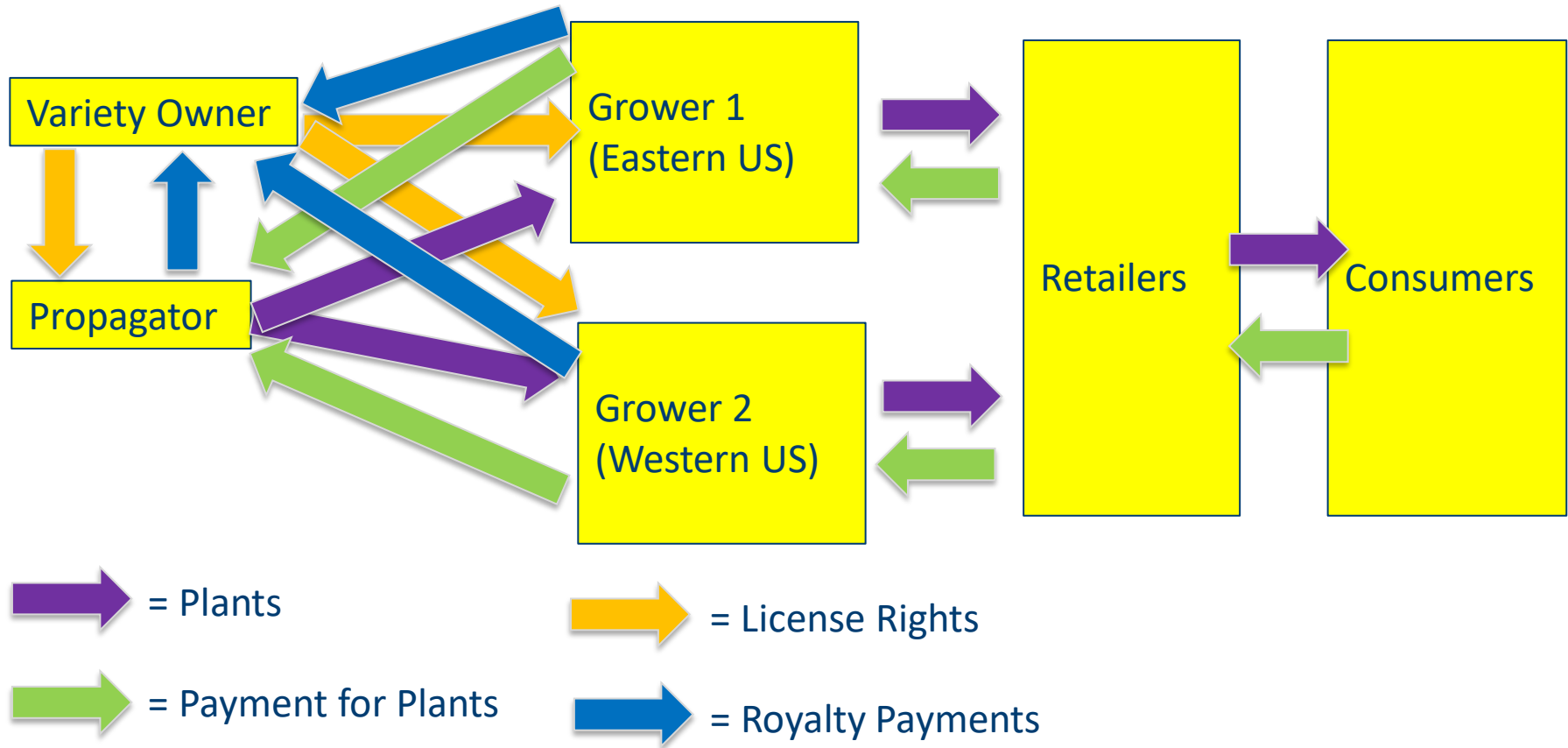
- Securing IP protection is just the beginning, not the end goal
- IP rights give you the right to exclude others from selling your patented variety and/or using your brand name
  - Can use that to just maintain a monopoly so that you are the only seller of that variety/brand
  - Can license your rights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

## Primary license considerations

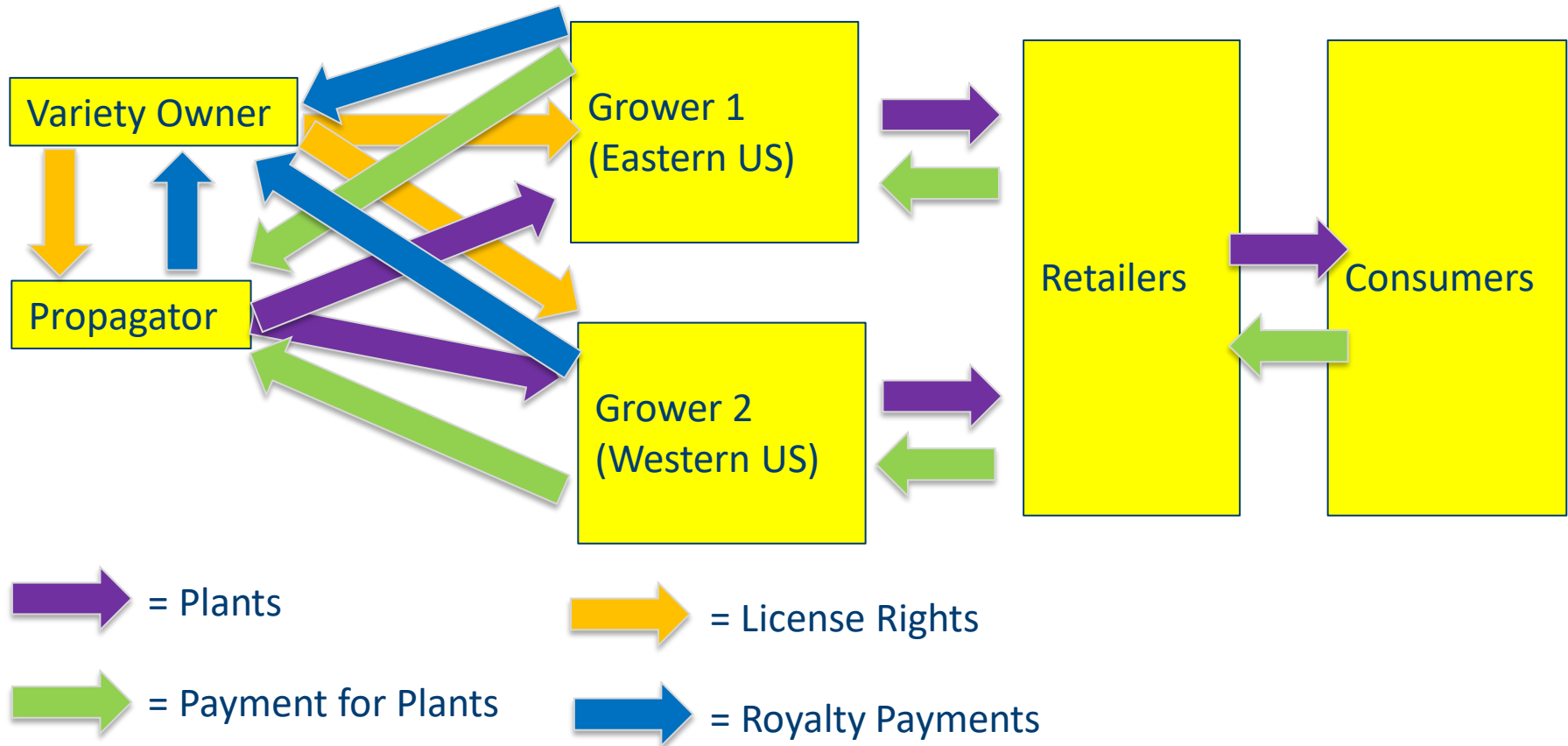
- What are your licensees doing for you?
  - Propagating plants? Generating seed? Selling flower?
  - Exclusive or nonexclusive? Exclusive in a particular territory?
- Need to think through the entire license scheme on the front end to make sure the proper licenses are in place



## Example license scheme



## Example license scheme



## Speakers



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PANITCH  
Intellectual Property Law  
SCHWARZE



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