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PLC | Global Intellectual Property

INTELLECTUAL PROPERTY AND LEGAL PERSPECTIVES ON NEW TECHNOLOGIES AND VARIETY DEVELOPMENT

SESSION III: ROLE OF IP RIGHTS IN SECURING INVESTMENT AND PARTNERSHIPS IN BREEDING

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• GOALS FOR COMPANIES FORMED AROUND BREEDING PROGRAMS

- Protect program and increase return on investment with:
 - 1. Systematic, structured breeding programs
 - 2. Certainty around ownership, FTO
 - 3. Enforceable against competitors





Protecting Breeding Programs

Michael T. Coe, Katherine M. Evans, Ksenija Gasic, Dorrie Main. **Plant Breeding capacity in U.S. public institutions.** *Crop Science*, 2020

- Declines in breeding programs nationwide, particularly research institutions and funded programs
- 21%+ decline in FTE for program leaders in 5 years
- 17%+ decline in FTE for technical support personnel
- Significant expertise nearing retirement (30%+ over 60 and 62% over 50)
- *Good news is that biotechnological methods (tissue culture, mutation breeding, DNA technologies, molecular breeding, gene editing) has resulted in development period decreasing to 4-11 years making plant breeding less time-consuming. Still just as expensive and expertise to do so is decreasing.*



PROACTIVE STRATEGY TO SAFEGUARD INTELLECTUAL PROPERTY

- Codification/Acknowledgement of Rights

- Patents
- PVP/PBR
- Trademark

- Interparte Agreements of Rights

- Internal – employee agreements, assignments, IP policies, invention disclosure forms
- External – Outlicensing – NDAs, MTAs, Bag tags, research agreements
Inlicensing- NDAs, MTAs, Bag tags, research agreements -FTO

Trade Secrets

know how, customer lists, databases



Asset	Intellectual Property
Breeding infrastructure, Selections, Results, Materials, Markers, Equipment, etc.	Know-How, Confidential Info, and/or Trade Secrets (and occasionally patents too)
Plants, plant parts, traits, proteins, genes (with exceptions), microorganisms, transformed cells, etc.	Patents (utility and/or plant)
Varieties, cultivars, inbreds, F ₁ hybrids	Patents (utility and/or plant), PVPs, and/or Trade Secrets
Brand name for source, variety, trait, etc.; Distinctive marks, logos, and packaging	Trademark; Trade Dress

General Forms of Legal Protection



Patents (Utility and Plant)

35 U.S.C. § 161-164



Plant Variety Protection Act Certificates

7 U.S.C. §§ 2321 et seq.



Material Transfer Agreements/Other Contracts



Restrictions of Use - Bag Tags/Sales Contracts



Trade Secrets

State Law (Uniform Trade Secret Law)

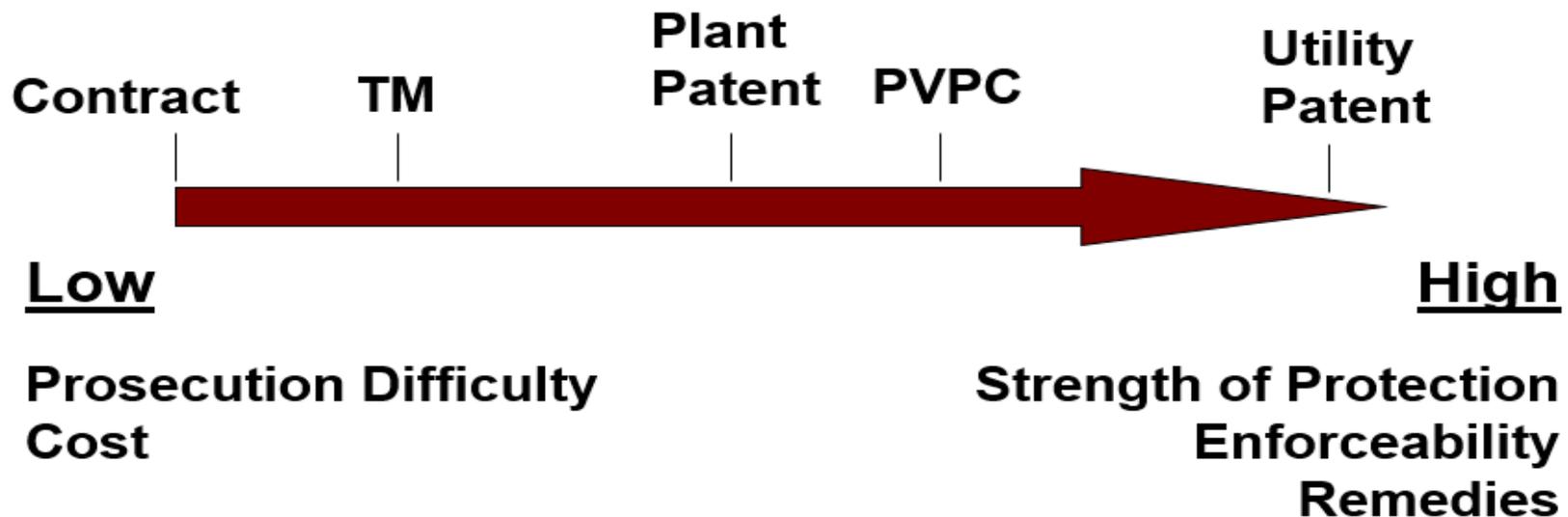
Defend Trade Secrets Act

•18 U.S.C. § 1836 (b)

Considerations in appropriating limited resources for IP Safeguards

Strike a balance among:

- Licensing strategy
- Industry expectations/common practice
- Costs vs. benefits
- Enforceability
- Scope of Protection



What Is a Patent Worth?

OCTOBER 16, 2019 • RESEARCH BRIEFS IN ECONOMIC POLICY NO. 185

Empirically, we find that the first patent increases a startup's chances of securing funding from venture capitalists (VCs) over the next three years by 47 percent, of securing a loan by pledging the patent as collateral by 76 percent, and of raising funding from public investors through an initial public offering by 128 percent. The VC funding effect is strongest for startups founded by inexperienced entrepreneurs and located in areas where attracting investors' attention is harder but is weakest for biochemistry startups. Mirroring the ambiguous effects of subsequent patents on the performance of startups, we find that the approval of a startup's second application appears to have no statistically significant impact on the startup's ability to raise VC funding.

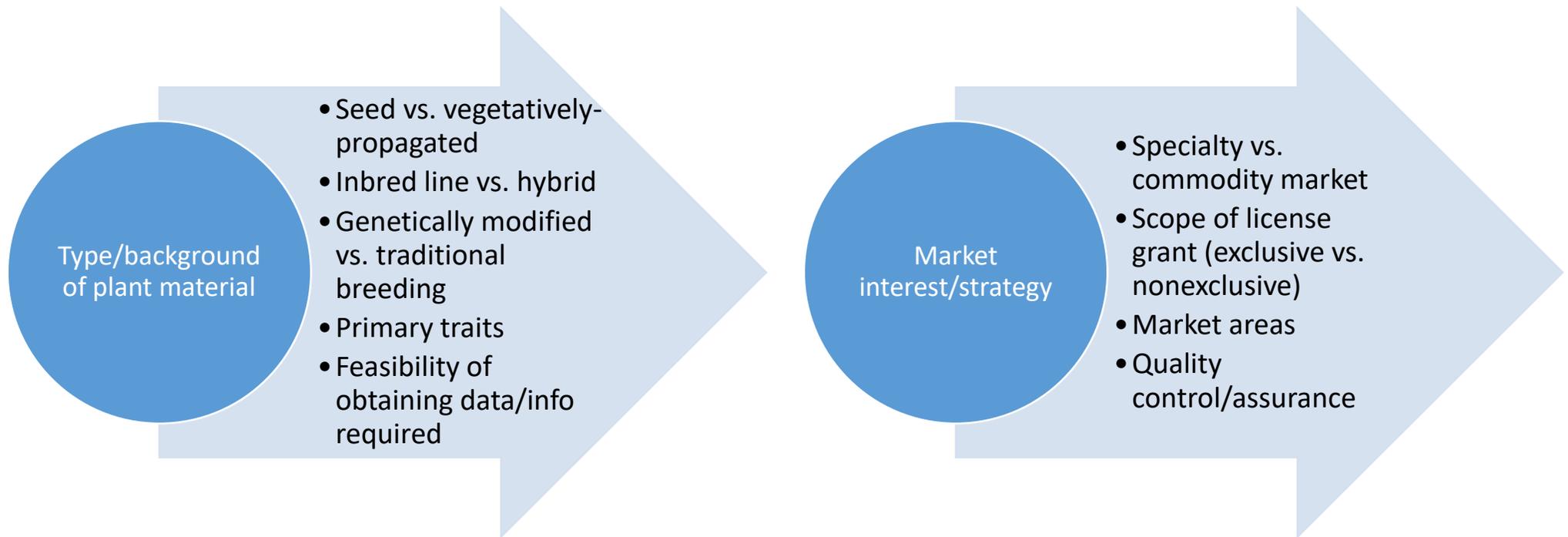


- *IP Identifier Tool for Identifying Valuable IP*
- **CHRISTOPHER HUSSIN | 02.08.23**
- The US Patent and Trademark Office (USPTO) recently announced the launch of the agency's new **Intellectual Property (IP) Identifier** tool. The tool is designed for those who are less familiar with IP, and it can be used to help identify whether a user has intellectual property and how best to protect it.
- The USPTO notes that companies significantly benefit from protecting their IP:
- Companies benefit from having IP protection. **When used as collateral, a company's first patent increases venture capital funding by 76 percent over three years and increases funding from an initial public offering by 128 percent.**

- It can also help serve as a recruiting tool: **The approval of a startup's first patent application increases its employee growth by 36 percent over the next five years.**

- Further, protecting your IP can also increase your market share – a new company with a patent increases its sales by a cumulative 80 percent more than companies that do not have a patent.

Considerations in choosing the right protection





Patents (Utility and Plant)– granted by USPTO

Requirements:

- Novelty
 - Consider Statutory bar date – for example, barred from obtaining a patent if the plant was commercially or publicly available more than one year prior to filing the patent application.
- Nonobviousness
- Written description
- Seed deposit with an approved entity (for utility patents)

Length of Protection

- 20 years from filing date

Type of Protection

- Exclusionary Right—to exclude others from making, using, or selling your claimed invention without your permission within the U.S.

Utility Patents

Broad protection-- Can be used to protect a new variety of plant that is reproduced either sexually (seed) or asexually (clonal) and can include coverage for varieties, plant parts, genes, traits, methods

- Benefit—Gold Standard of protection—Exclusionary right covers making, using or selling your particular cultivar and its derivatives (F1 hybrids, mutants, etc.)
- Detriment—higher cost; usually takes 2-3 years from filing to allowance; you cannot add to disclosure post filing without encountering written description issues
- Application must include— Detailed botanical description plus information to support claims regarding mutagenesis, genetic engineering, crossing, etc.

PITFALLS AFFECTING VALUE OF PATENTS

- Chain of Title
 - Patent Assignments- from inventor/ Owner to company
 - Make sure all are in place- bound and clearly set out obligations in employment contract
 - No clear policy for sharing of revenue, rights of employee or owner inventors
 - Freedom to Operate
 - Where did breeding material come from?
 - Rights of all materials used, starting materials, machines, methods (CRISPR) devices used etc.
 - Right to practice invention – patent rights are exclusionary

IP Assignments – A Trap for the Unwary!



- To enforce a patent, one must have “standing” – a legally protected interest that is harmed by infringement
 - Only owners (including assignees) and certain exclusive licensees have a protected interest
 - Only owners (including assignees) can file suit
 - In the case of multiple owners, ordinarily *all* must consent
- Breeder-inventors must *fully and completely* assign their rights in their inventions to their employers to ensure that the patents can be enforced (often years later) without the involvement of the inventors
- Assignment language can be automatic, but it must clearly accomplish an actual transfer of ownership – not just a contractual promise to make an assignment in the future.
 - “I hereby assign” / “I hereby grant” = OK
 - “I will assign” / “I agree to assign” = NOT OK

US Plant Variety Protection Act Certificates Issued by USDA

Moderate Value—Can be used to protect sexually and asexually (since 2018 Farm Bill) reproduced plants : can cover varieties, seeds, tubers, asexually reproduced plants

- Benefit—Less expensive than utility patents (although can be more than Plant Patents); relatively quick from filing to allowance; high allowance rate; no ongoing maintenance fees; may specify seed certification
- Detriment— Scope of Protection: (1) not as strong as patents (breeding and farmer-saved seed exemptions); (2) Judicial determinations are sparse; (3) Research Exemption – lack of judicial direction – is it limited to research or may it protect a party using a PVPA protected variety as parent material in a commercial breeding operation.

Plant Breeders Rights – Foreign

- Rights granted to the [breeder](#) or owner, similar to rights provided by US PVP
- [Exclusionary right](#) over the propagating material (including [seed](#), cuttings, divisions, tissue culture) and harvested material ([cut flowers](#), fruit, foliage) of a new variety for 20 years (25 years for trees and vines) from issuance
- A variety is:
 - New - not been commercialized for more than one year in the country of protection
 - or anywhere for 4 years or 6 years for trees or vines
 - Distinct - differs from all other known varieties by one or more important [botanical](#) characteristics
 - Most countries require growth trials by state agency to establish
 - Uniform - consistent within the variety;
 - Stable - genetically fixed
- Annual Maintenance Fees usually required

§ 2544. Research exemption

- The use and reproduction of a protected variety for plant breeding **or other bona fide** research shall not constitute an infringement of the protection provided under this Act.
 - Bona Fide Requirement Applies to “Use”, “Reproduction” and “Research”
 - If Parental Material is Used Without Permission - Contrary to an MTA or Restrictions of Use Clause or Purloined is this Bona Fide Use?

EMPLOYMENT CONSIDERATIONS

Goal for incoming employees: buy in to protection efforts & avoid contamination with others' IP



Education

Assess incoming know-how/materials

Restrictive covenants



Goal for departing employees: reminder of protections, restrict losses of IP

- Education
- Notice to new employer
- Monitoring releases from competitor

What Forms of Management



Material Transfer Agreement



Restrictions of Use – Bag Tags & Sales Contracts



Trade Secrets

Material Transfer Agreements

- In Intellectual Property Management in Health and Agricultural Innovation: A Handbook of Best Practices (2007) (eds. A Krattiger, RT Mahoney, L Nelsen, et al.). MIHR: Oxford, U.K., and PIPRA: Davis, U.S.A. Available online at www.ipHandbook.org:
- Fundamentally, an MTA is a bailment, that is, a transfer of tangible property without transfer of title. Under such an agreement, the provider maintains ownership of the property transferred. Transferred property is held by the receiving party according to terms stipulated in a legally binding contract. The contract, therefore, governs the transfer of tangible biological materials between two or more parties.

Restrictions of Use

“The soybean seed in this bag contains genetics developed, licensed or owned by Seller. All rights to make, produce or sell seed products derived from this seed reside solely with Seller. Buyer acknowledges this ownership and agrees to the following conditions: ... Buyer will not resell or supply any of this seed to any other person or entity. Furthermore, Buyer is strictly prohibited from saving or selling, for seed purposes, any gain products from this seed. Buyer further agrees not to alter, or permit the alteration of the seed ... through either genetic engineering, conventional breeding activities or other techniques.”

Trademarks

- Requirements:
 - Trademarks must be distinct—they cannot be generic (i.e., the cultivar/variety name) –DO NOT USE a chosen TRADEMARK as the variety name in a patent/PVP or in any marketing materials.
 - Trademarks cannot be confusingly similar to anyone else's trademark name – consider trademark searching before adoption
 - If the mark is highly descriptive of the characteristics/traits of the variety, it may not be protectable at least without extensive, substantially exclusive use.
- Length of Protection—Potentially forever so long as mark is used
- Type of Protection
 - Can stop third parties from using your exact trademark or a mark that is confusingly similar in sight, sound and/or meaning within the same or a related trademark class (goods/services).

Trade Secret – Hidden In Plain Sight?

- **“Reasonable Efforts to Maintain Secrecy”**
 - Employee NDA/Confidentiality Agreements
 - Company Training on IP/Proprietary Protection
 - Restrictive Use Language in Production Agreements, Foundation Seed Agreement, Associate Agreements, MTAs
 - Restrictive Use Language on Bags/Tags/Paperwork for Bulk Seed
 - PVP/Patent Notice
 - For PVP—using “Unauthorized Propagation Prohibited” or “Unauthorized Seed Multiplication Prohibited” and after the certificate issues, such additional words as “U.S. Protected Variety
 - For Patent – using “Pat. No. X,XXX,XXX” or “Patent X,XXX,XXX” on product or “Pat. No.:www.domainname.com/patents” (and listing patent numbers next to SKU numbers or other clear designation on webpage)



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