Guidebook of IP/Technology Transfer

Track 3
Advanced-Level Technology Transfer

Topic 3.13.1

Plant Breeding & the TTO

IP/bioproperty

As a tool:

IP/bioproperty is like a hammer in the hands of a carpenter

Without a carpenter, the hammer is useless

Without a hammer, the carpenter cannot build

Most importantly,

the point isn't the hammer…..

or the carpenter ……..

It's building the house

Importance of IP/Bioproperty

Why is Property so critical to invention, new technology, and innovation?

- New technology almost always requires money/investment to create and develop
- Investment requires a return (ROI)
- ROI requires an asset, and its control
- Property = control of an asset
- IP/bioproperty = lifeblood of plant breeding industry

Importance of IP/Bioproperty

Why is Property so critical to invention, new technology, and innovation?

- Innovative business models typically require control of technology

Example: organized value chains of proprietary fruit varieties

- Control necessary to structure and incentivize partnership systems

Example: licensing schemes underlying joint venture arrangements

Presentation today

- Technology licensing defined & licensing basics
- Importance of the “Property Control Position”
- Licensing in the seed industry
- Plants as property: the foundation of licensing
- Tangible vs. intellectual property
- Elements of a Plant License
- Developing license terms
- Special considerations for licensing plant traits, lines, varieties

Technology licensing defined

- Based on property in technology
- Transfers use-rights, not ownership

  (rent not sale)
- Licensing = “renting” technology property under defined terms and conditions
- Terms & conditions highly flexible, easily tailored to suit Licensor and Licensee
- Much easier to value technology than with one-time sale price
- Reliance on contracts, partners, trust

Importance of the "Property Control Position"

Property = the right to control

Control

that assures:

interests protected

effective transactions

return on investment

(the "quid" in *quid pro quo*)

What is the Property Control Position?

- An umbrella term that covers different types of property
- A technology is usually controlled using more than one type of property
- The Property Control Position is a suite of property types

Plants as Property: *the foundation of licensing*

Property = the fundamental right to control

Possession
Use
Sale, lease, rent, license, etc
Gift or donate
Transfer, withhold, destroy

Property = fundamental to business transactions, investment, value, etc

Plant Property types:

tangible
intangible
intellectual

Technology Property relevant to plant breeding

Intellectual Property

- Plant Breeder's Rights (patent-like, exemptions, single line protection)
- Utility patents on traits (Europe, US)
- Utility patents on lines (US)
- Trade secret (parental lines, breeding pedigree, breeding methods)
- Trademark, Certification Mark
- Geographical Indications

Technology Property relevant to seed industry

Tangible Property

- Bioproperty (personal property rules)

  seeds, cuttings, plants, tissues, DNA
- Physical controls

  fencing, locks, security measures

Indirect Property mechanisms

- Regulatory devices (e.g., seed certificates)
- No-Trespass laws

Defacto property

- Hybrid seed

Property-like Regulatory Devices

Permits (import, testing, etc.)

Seed certification “tags”

Registrations

Bioproperty

- Tangible biological material (plants, parts, seeds, tissues, DNA, etc)
- The law considers possessor of tangible property to be the presumptive owner……

unless:

the owner has transferred right to possess

in a bailment

or…

the property has been stolen (or lost)

Protecting Bioproperty rights

- Requires physical management
- Control of access and possession, via bailments (Material Transfer Agreement)
- Can be licensed, sold, traded, gifted, etc
- It can become public domain if not careful
- Labelling, tracking, monitoring, well-managed inventories

Bailments

Transfer right of possession,
but **NOT ownership**

universal applicability of personal property rules

Courts assume possessor is one of the following:
the owner, a "bailee", or
a thief

Seeds, whole plants, plant parts, tissues,
cell lines, DNA

UPOV-type
Plant Breeder's Rights

"PBR"

Protects only individual lines

- Allows breeding and research by others
- Most countries have a farmer's exemption to save seed
- Medium cost

Typical Intellectual property in plants

Whole plants and seeds

UPOV model

right to stop propagation, selling the variety, allows breeding use

…….but

covers "Essentially Derived Variety"

exemptions for farmers, breeders, researchers

schedule of protected crops

Trademarks & Certification Marks (US)

Geographical Indication/Denomination

Trade secret (pedigrees, parental lines)

Intellectual property in plants

Plant parts

propagules covered by PBR

genes, genetic constructs, methods, etc. are patentable if they satisfy basic requirements of novelty, inventiveness, utility

a patent on a gene (or other DNA component) gives the owner the right to stop others from making, using, selling whole plants with that gene **inserted.**

Trade Secret

- Parental lines
- Breeding pedigrees, breeding methods, propagation methods
- No filing; low cost
- Requires management of confidential information and limited access to bioproperty

Trademark & Certification Mark

- Low cost to create
- Costly to build a brand
- Essentially perpetual
- Requires policing of use
- Can be highest value IP

Trademark vs. Certification Mark

Trademarks (TM)

- used by the owner on products in the marketplace

Certification Marks (CM)

- not used by the owner; owner supervises CM marketplace use by others
- Can be used like a GI in the U.S.
- can be applied to create/capture value of unique ag products in U.S. markets

Geographical Indication (GI)

- is a symbol/insignia used on products that have a specific **geographical** origin and possess qualities or a reputation that are due to that origin.

- In order to function as a GI, a symbol must identify a product as originating in a given place.

GI Treaties

- ***Lisbon Agreement*** *for the Protection of Appellations of Origin and their International Registration*
- ***Madrid Agreement*** *Concerning the International Registration of Marks*
- WIPO's CLEA database
- No GI in the US

  use Certification Mark

Plant Property

Control Position

Creation and strategic management

- typically involves a unique suite of integrated property types
- combination of bioproperty, PBR, trade secret, trademark, patent
- geography usually plays important role (remember that IP is national in scope)

Other Plant Breeding IP Assets

- **Breeding methods**
  (patents and/or trade secrets)

- **Breeding tools**
  (patents and/or trade secrets)

- **Molecular markers**
  (patents and/or trade secrets)

Other Plant Breeding IP Assets

Breeding methods

US Patent no. 9,565,827

Brassica campestris var. pekinensis Hongbaechoo as a new variety of plant and a method for breeding the same

US Patent no. 9,107,355

Real-time process for targeting trait phenotyping of plant breeding experiments

US Patent no. 9,668,439

High yielding soybean plants with low linolenic acid

Impacts of New Technologies

CRISPR/Cas 9

- Is it a GM technology?
- It will generate a huge number of new
  - lines/technologies
  - patents
    - PBR
      - other?

IP/Bioproperty Strategy

Plant Breeding Examples

Ramot Wheat Rust Resistance

- **Tel Aviv University wheat breeders**
- **Ramot (technology transfer arm of TAU)**
- **Leaf & Stripe Rust Resistance in Wheat**
- **The Technology:**

Wheat lines with dual resistance to leaf rust (*Puccinia triticina*) and stripe rust (*Puccinia striiformis*).....

.....made through a unique method of introgression of rust resistance traits from Sharon Goatgrass (*Aegilops sharonensis*) into *Triticum aestivum*

Ramot Wheat Rust Resistance

The Technology

- 6 lines of *Galil* with dual resistance trait
  (plants, seeds, tissue culture)
- Greenhouse and field data from trials in 7 countries
- "Chromosome Engineering" method
  overcomes barrier to transfer traits from
  Goatgrass (wild species) to wheat

Ramot/Tel Aviv Wheat Rust the Property Tools

6 lines of *Galil* with the dual resistance trait

- ✓ Bioproperty

Breeding pedigrees, greenhouse and field data

- ✓ Trade Secret (careful publication)

“Chromosome Engineering”method

- ✓ US, Canadian, EU patent applications

Potential varieties

- ✓ PBR
- ✓ Utility patents in US

Ramot/Tel Aviv Wheat Rust the Property Tools

US Patent Application 20160222406A1

Claim 1:

A wheat cultivar suitable for commercial growth comprising a genetic element comprising a segment of Aegilops sharonensis chromosome 6S^{sh}, wherein the segment confers or enhances resistance of the wheat cultivar to a disease selected from the group consisting of leaf rust, stripe rust or a combination thereof.

"Ramot Wheat Rust Resistance

The public good

- Further the mission of Tel Aviv U. and its wheat breeding program
- Manage the technology as a good
  - "breeder-citizen" and academic institution
- Work with ethical private sector partner
- Collaborate with non-profit sector
- Philanthropic aspects?
- Revenue from commercialization

IP/Bioproperty Strategies:

Look for Opportunity

- IP/bioproperty has strategic business value (not just defensive/offensive)
- Consider looking for traits in your program that may have value outside typical commercialization routes
  - Are you considering other business models?
  - Different types of business partners?

Think outside the box: IP/bioproperty use has multiple possibilities

IP/Bioproperty Strategies:

Look for Opportunity

- Have you reflected on various aspects of the various value chains relevant to your IP/bioproperty assets?
- Is there a market pull from parts of the value chain that would value traits in the program not typically pursued?
- Will you consider and address future trends?

Think outside the box: IP/bioproperty use has multiple possibilities

IP/bioproperty strategy:

sale or license

Sale

typically one-time transaction

challenging to arrive at value

License

ongoing relationship

easier to share risk/return

Licensing defined:

terms can be tailored

Scope of Licensee's rights to use

academic (no commercial intent)

- breeding exchanges
- research

commercial

- testing/evaluation only
- breeding exchanges

Licensing defined:

terms can be tailored

Scope of Licensee's commercial rights:

testing only

breeding

scope limited, or unlimited

sales only

breeding and sales

etc., etc…..

Licensing defined:

terms can be tailored

Scope of Licensee's rights:

"genetic engineering" allowed?

finding genetic markers allowed?

Licensing defined:
terms can be tailored

Scope of Licensee's commercial rights:

sales defined

territory

time-limited?

sales and breeding

- All financial terms negotiable

  license fees, royalties, milestones, minimum annual sales, etc.

Licensing defined:

terms can be tailored

The license may contain any other terms that suit the parties:

- technical collaboration
- sales & distribution cooperation
- use of trademarks
- technology exchanges
- personnel exchanges
- etc., etc., etc……

There are few rules limiting what the parties can include in the license

Licensing as a Strategy

Licensing Out (by technology owner)

- Can create multiple revenue streams, spreading and sharing risk with partners
- Useful in markets where you don't have the capability or strategic interest; expands market share
- Many approaches: by territory, field-of-use, consortia, etc….

Licensing Tangible/Personal Property

The license agreement including tangible/personal property as part of an IP/tangible property asset license

- The tangible property and intellectual property (most likely patents, maybe trade secret too) to be defined distinctly and separately – in the *Definitions* section
- The license should make it very clear that the license is a bailment only – licensor retains perpetual ownership throughout licensee's possession
- In the *Grant* section, licensor will grant separate use rights to each type of property
- In the *License Fee* section, the fee may be comprised of two separate fee-components, one for tangible property, the other for IP – at licensor's discretion

Licensing as a Strategy

Licensing Out (by technology owner)

- Consider business opportunities outside of main business focus
- Can maximize return on R&D investment and intellectual assets
- Think creatively and beyond only support of main product/service
- May create opportunities for technology exchanges

Licensing as a Strategy: "hidden opportunities"

The Spinach story

- Review of breeding assets with CEO and head-breeder of leading spinach seed company
- Their view: IP is a problem; how to protect themselves (a defensive strategy)
- Encouraged thinking "outside the box"

  (IP as strategic, business development tool; (an offensive strategy)
- Unexpected assets discovered

Licensing as a Strategy

Licensing Out

If you are a non-profit technology creator/owner

(i.e., university, government)

Licensing-out is likely your only option for commercialization of your technology

(unless you sell your IP – not advised!)

Licensing as a Strategy

Licensing In

For companies:

- Access to new technology and technical capabilities
- Takes advantage of others' investments in R&D
- Technology exchanges

  (cross licensing, etc)

Licensing as a Strategy

licensing vs. sale

- no ownership transfer
- smaller lump sum payments…

  but, ongoing revenue
- maintains involvement, stewardship, control, ownership
- creates long-term relationships

  (good for technical collaboration)
- license terms can be tailored to

  situation
- extended exposure to liability

Licensing as a Strategy

Developing a licensing policy

exclusive vs. non-exclusive,

geographical scope, field of use

paid-up, milestone fee, royalty

commercial development obligations, (stewardship, etc)

philanthropic, humanitarian considerations

Cornell as example

Company examples

Licensing Basics

- based on the Property Control Position
- licensor retains ownership
- definition of property (the “licensed property”)

bioproperty

plants, seed, tissues,
quantities, labels, details…..

IP

PBR, patents, trade secrets,
trademarks

IP-like

registrations, etc.

Licensing Basics

- **grant of rights**

  possession and use (breeding?), sales, exclusivity, territory, field-of-use

- **financial terms** (fees, royalties, cost reimbursement)
- **enforcement:** piracy and infringement

Licensing Basics:

design principles

Licensee and Licensor mutually

design a method for capturing value in the marketplace and reasonably share that value between themselves

Design constraints include

the crop(s)

the technology (trait)

the industry, the market,

licensee's business model,

property control position

Licensing Basics

- **Licensee obligations** include

  milestones, payments, legal use, records, licensor may inspect and audit, quality control, other

- **Licensor obligations** include

  property right protection, quality of original material, true ownership, other

- **Licensee & Licensor**

  negotiate the allocation of market-place risk and liability

Licensing Basics .....continued

- **dispute resolution mechanism**
- **term, and termination protocols**
- **special situations**

  future developments, data sharing, vendor relations, technical collaboration, joint inventions, etc.
- **other details**

  jurisdiction, use of names, confidentiality, legal "boilerplate"

Plant Licensing:

key parameters configure structure

- **What is the property?**

  bioproperty and/or IP

- **What value does it have in the market?**
- **Where does it fit in the value chain?**
- **What licensing strategy will allow optimum value capture?**

  exclusive or non-exclusive

  by crop, use, territory

Plant Licensing:

thinking outside the box

The Cornell "Red Potato Story"

- Cornell tradition of breeding for NY potato growers
- New, red-flesh potato variety ready for release
- NY potato growers not interested (no market)
- Idea: create some market pull
- License to retailer

  "patriotic potatoes" (red, white, & blue)
- Retailer-licensee sublicenses to select growers

Plant licensing: *the approach*

- **define the purpose of the licens**e:

  non-profit, research, commercial; evaluation/testing,

  breeding of traits, sales of varieties

- **tailor license to fit the licensee's business model**

  sale of lines, hybrids, fruit vs plants,

  etc., licensee's involvement (sales) with the value-chain

Plant Licensing: *the approach*

- Given crop type, property suite, and
  market-place value of the property
- balance market value with risk
- industry norms for licensing
  types of fees,
  royalty structure & amount

Plant Licensing....continued

- **fields of use**

  fresh market vs processed,

  food vs industrial

  consider the licensee's role in the supply/value chain

- **territory and nature of exclusivity**
- **limits on uses** (may affect fees/royalty)

Managing Plant Bioproperty

Tangible property controls should be the cornerstone of any plant breeding and development program

- Maintain accurate inventory (always know where all your materials are)
- Possession by other parties always requires a bailment and record
- Respect (and keep a good record) others' bioproperty

Licensing Plant Bioproperty

Bioproperty controls can be problematic:

When it runs counter to industry tradition
when the property is the item of commerce
when the property is sold widely
tradition of public access to food crops

National biodiversity laws can also be an issue

National Biodiversity Laws

Convention on Biodiversity (CBD)

(signatories recognize the rights of states to assert sovereignty over their biodiversity)

Some countries have a single, national biodiversity law (e.g., India),

others do not (e.g., U.S.)

National Biodiversity Laws: Some are evolving

The Philippines story

Nagoya Protocol implementation

"ABS" systems required of signatories

(Access & Benefit Sharing)

The Nagoya Protocol on Access and Benefit-sharing - Google Chrome

https://www.cbd.int/abs/

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25 YEARS Convention on Biological Diversity SAFEGUARDING LIFE ON EARTH

The Convention | Cartagena Protocol | Nagoya Protocol | Programmes | Information | Secretariat

Nagoya Protocol

About the Nagoya Protocol

Nagoya Protocol Text

History

Parties

Becoming a Party

List of Parties

National information - country profiles

Key Steps towards implementation

Key Protocol issues

ABS Clearing-House

> Access and Benefit-sharing

The Nagoya Protocol on Access and Benefit-sharing

Nagoya Protocol on Access and Benefit-sharing

Booklets available in:

Ar | En | Es | Fr | Ru | Zh | Courtesy Translations

The *Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity* is an international agreement which aims at sharing the

Ratifications

With the accessions by **Estonia** and **Nepal**, the Nagoya Protocol has 116 ratifications/accessions.

Nagoya Protocol Countries

Albania, Belarus, Benin, Bhutan, Botswana, Burkina Faso, Burundi, Comoros, Côte D'Ivoire, Denmark, Egypt, Ethiopia, European Union, Fiji, Gabon, Gambia, Guatemala, Guinea Bissau, Guyana, Honduras, Hungary, India, Indonesia, Jordan, Kenya, Lao People's Democratic Republic, Madagascar, Mauritius, Mexico, the Federated States of Micronesia, Mongolia, Mozambique, Myanmar, Namibia, Niger, Norway, Panama, Peru, Rwanda, Samoa, the Seychelles, South Africa, Spain, Sudan, Switzerland, the Syrian Arab Republic, Tajikistan, Uganda, Uruguay, Vanuatu, and Vietnam

International Bioproperty Access &Technology Transfer

- Determine the necessity of biomaterial transfer
- Make sure ownership is clear and true
- Consider the need for Material Transfer Agreements (bailment contract)
- Understand and properly execute the export and import regulations for the bioproperty

Material Transfer Agreements *(MTA's)* *and other bailment contracts*

The MTA:

- transfers possession, not ownership

  written or implied

- routinely used to exchange plant materials

  (research and breeding exchanges, commercial evaluations)

- restricts distribution
- defines uses and disposition on termination
- may or may not include fees

Material Transfer Agreements *(MTA's)* *and other bailment contracts*

The MTA:

- Allows exchanges without license negotiation

  keeps commercial license option open;

  maintains ownership over time

Strategies for Property Control and Management

- Every technology is unique
- Each technology will have a unique suite of property control mechanisms

Strategies for Property Control and Management

Developing the property control suite:

1. identify all possible property control tools available for the technology
2. assess each property control tool for cost effectiveness given technology's marketplace use
3. link potential property control tools with business strategies
4. consider geographic aspects
5. select the most cost-effective property controls
6. Implement and adjust, as necessary

Plant License Elements

- the parties defined
- plant property defined
- grant of rights (exclusivity, field of use, territory, sublicensing)
- license fee defined precisely
- royalty defined (type, amount, schedule)
- milestones (events-based or scheduled payments)

Plant License Elements
.....continued

- quality controls
- special situations
- records & audits
- market monitoring & enforcement
- term & termination, bioproperty disposition
- dispute resolution

Developing License Financial Terms

- scope of rights
- size of market
- value capture mechanisms
- value of product in market place
- profit margins
- contributing value of licensed “technology”
  to product sold
- overall understanding of mutual rights, obligations, responsibilities
- industry standards

Developing License Financial Terms

The license fee

(the rational basis)

- development cost approach
- income method (market projections and NPV)
- cost recovery
- effect of “bidders”
- one time vs scheduled
- consider non-cash compensation

Developing License Financial Terms

Royalty

(typically a % of net sales)

- gross margins
- enabling value
- industry standards
- accounting feasibility
- monitor for sustainability
- future adjustments in good faith

Special Considerations for Plant Licenses

Varieties:

usually straightforward, easy to track

Traits:

not licensing a product;

licensor's technology embedded in licensee's valuable genetics

Germplasm:

be aware of genetic contribution of value

Special Considerations for Plant Licenses

Varieties:

licensing terms relatively easy

Traits:

tracking is a challenge

royalty structure can be complex

Germplasm:

Royalty schedule typically based on % of genetics contributed

Special Considerations for Plant Licenses

Hybrids:

Control of genetics more feasible

Open Pollination:

may need to “sunset” royalty on trait

Some "Tricks of the Trade"

- Be as creative as you need to be to create a "win-win" structure for each party
- But, don't be more creative than necessary
- Create good rapport with your partner through the license negotiation process

  (you'll probably need it later)
- Designate someone to be the "caretaker" of the partnership

Some “Tricks of the Trade”

The license is a “living” document – it can (and should) be modified as conditions change

A license is like a marriage

Case Study: tomato trait

The Technology:

- Select tomato lines exhibit significant repellency to sucking insects (and viruses they carry)
- Repellency caused by high production of acyl-sugar exudate from trichomes on chlorophyllous surfaces
- Acyl-sugars repel sucking insects
- Breeder developed 30 lines that all strongly exhibit this repellency trait
- None of the 30 lines are suitable as commercial lines (due to agronomic and/or fruit flaws)
- The trait easily bred into other lines; all are good parental lines

Case Study: tomato trait

The Potential Property Position ("PPP")

Intellectual Property

- PBR on individual lines possible, but expensive; don't know which line or lines to protect
- Utility patent possible on trait (US, EU only)
- Trademark on trait possible
- Trade secret on breeding pedigree
- Copyright on notebooks, spreadsheets, pedigrees, documents

Tangible Property

- MTA maintained for all transfers of whole plants, seeds, cuttings, and *in vitro* tissues
- Notebooks, documents

Case Study: tomato trait

Your Assignment

Optimize the commercial value of the technology asset by

- **Designing a Property Control Position**

  that supports your licensing strategy

- **Defining a licensing strategy for:** a) India; b) globally

Assumptions

- You have no interest in your own selling in the tomato value chain; you must have a global licensing strategy
- you have unlimited IP budget;
- your goal is to maximize the return/cost equation;
- you have kept very tight control over all materials of the 30 lines (only you have ever had possession)

Track 3
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Thank you