Intellectual Property Rights
Why, What, and How?
Susana Goggi
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ISU

The resource outlook to 2050
By how much do land, water use and crop yields need to increase by 2050?
by Jelle Bruinsma Consultant, ESA, FAO http://gfs.wur.nl/docs/Bruinsma_pres.pdf

US Maize Yields 1866-2016 (USDA)

1) Innovation requires investment
2) Intellectual Property provides temporary rights to exclude others from freely using what has been developed from research so providing the opportunity to recoup investments

Trade Secrets
- E.g. Know-how, proprietary methods, proprietary inbred lines
- Must take steps to maintain the trade secret
  - Not disclose publicly
- May not protect against reverse engineering
- No expiration unless lost through disclosure
- ISF regards proprietary inbred lines that may be present in a bag of hybrid seed to be the property of the breeder who developed those inbreds.
**Patents**

- **Plant Patent (Plant Protection Act 1930)**
  - Very similar to a PVP BUT only for asexually propagated non-tuberous species

- **Utility Patent**
  - DUS + innovative step + disclosure
  - Products, Processes (methods)
  - Maize variety per se first patented 1985
  - Patented herbicide resistant soybeans 1996
  - Requires license from owner for any use
  - No breeder exception in the US
  - Placed in public domain at expiration

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**Patentability of Plant Varieties: USA**

- **1980** Diamond v. Chakrabarty
  - Ananda Chakrabarty developed a bacterium (Pseudomonas) capable of breaking down crude oil and proposed for use in cleaning up oil spills
  - Turned down by patent examiner as the law dictated that living things were not patentable
  - US Supreme Court upheld patent (5:4 vote)
    - A live, human-made micro-organism is patentable subject matter and constitutes a “manufacture” or “composition of matter”

- **1985** USPTO Board of patent appeals (re Hibberd)
  - Plants are within meaning of “manufacture” or “composition of matter”

- **2001** US Supreme Court (J.E.M. AG Supply, Farm Advantage v. Pioneer Hi-Bred International)
  - Confirmed that Utility patents may be issued for plants
  - Neither PVP nor the PPA preclude granting utility patent coverage to plants

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**IP Promotes Licensing & Research Relationships to Create More Diversity of Better Products for Farmers**

- Monsanto
  - Roundup Ready – Glyphosate Tolerance
  - YieldGard CB – Corn Borer
  - YieldGard RW – Corn Rootworm
  - YieldGard VT – Fall Armyworm

- BASF
  - Research Collaboration
  - SmartStax

- Bayer
  - LibertyLink – Glufosinate Ammonium Tolerance

- Syngenta
  - Agrisure GT – Glyphosate Tolerance
  - Agrisure CB/LL – Corn Borer

- Dow
  - Herculex – Corn Rootworm, European Corn Borer, Western Bean Cutworm and Black Cutworm

- Pioneer
  - LibertyLink license
  - Herculex license
  - Agrisure license
  - Research Collaboration

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**Trait Licensing US 2013-2014 enabled by IPP**

- **Maize**
  - 85% area GMO
  - 47.2% market share trait developers
  - At least 52.9% market share: licensed traits

- **Soybean**
  - 95% area GMO
  - 41.9% market share trait developers
  - At least 58.1% market share: licensed traits

(Sources: trait area USDA 2013; market share Farm Journal)

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**Patents**

- **More effective IPP than provided by PVP**
  - No farmer exemption
  - No breeder exemption
  - Unless specified in patent law (France and Germany)

- **Encourage more investments in R&D**
  - Especially significant for self-pollinated crops
  - E.g., soybeans in the US
  - Encourages research into scientific basis of performance
  - Increased understanding of the genetic basis of agronomic traits

- **Allow longer-term, higher-risk R&D by private sector**
  - PVP not best suited to encouraging R&D to access exotic germplasm to develop a broader germplasm base
  - Transgenic traits likely not developed without utility patent protection
One size IP environment does not fit all

US
- Patents available on traits AND varieties per se
- DUS + innovation + enabling
- Provides full range of IP - allow inventor/breeder to select one or more
- Access-related protection (patent) clearer than EDV
- Research exemption in patents is VERY narrow
- MUCH licensing of germplasm and traits

Europe
- NO patents on varieties per se
- Limited to products
- Patents available on traits
- But not if essentially biological process — ie crossing
- Limited Breeder exception FR DE
- and unitary patent law (allowing access to underlying non patented germplasm)
- Exception scope in UP unclear
- PVP main instrument
- Less protection as technology facilitates access and quicker use
- EDV complex, time-consuming, can work around

Plant Variety Protection PVP
Plant Breeders’ Rights PBR
- Provides protection against Copying, Repeated Use, and Plagiarism (cosmetic breeding)
- Does NOT prevent
  - FURTHER BREEDING and COMMERCIALISATION
    - Other than from cosmetic or plagiaristic breeding via the EDV concept
  - FULL PROTECTION AGAINST FARMER RE-SEEDING
    - Farmer exemptions
      - Can be restricted to small farmers (in the EU, not in the US)
      - Can require a royalty payment (in the EU, not in the US)
- PVP provides less protection than patents, but quicker dissemination

UPOV Membership (74) April 2016

Contracts and Licenses

In the U.S., courts have found that “bag tags” (like shrink wrappers) can effectively license “one time use” of plants or seeds. See Pioneer Hi-Bred Int’l, Inc. v. Ottawa Plant Food, Inc., 283 F. Supp.2d 1018, 1035-1049 (N.D. Iowa 2003). “The bag label and bag tag unambiguously grant only a right to use the seed … to produce grain or forage; the label and tag unambiguously do not grant a buyer the right to resell [patented] seed.” Id

Agreements determine: Access, terms, restrictions

Trademarks
- Protect Brand
- Farmer Value
- Farmer Confidence
- Company Value

Open Source Seed Initiative
see https://youtu.be/f9NGG1ICwoo

- Members of the group are unhappy with the patenting of plant varieties, as they say the patenting of seeds restricts plant breeders’ freedom and increases the power of large seed companies.
- Taking inspiration from open source software, the OSSI seeks to create a “protected commons” of open-source seed varieties as an alternative to patented or otherwise legally restricted seeds.
- Pledge not to obtain IP at all on varieties developed and so allow:
  - The freedom to save or grow seed for replanting or for any other purpose.
  - The freedom to share, trade, or sell seed to others.
  - The freedom to trial and study seed and to share or publish information about it.
  - The freedom to select or adapt the seed, make crosses with it, or use it to breed new lines and varieties.
Objectives of Intellectual Property Protection in Agriculture

- Provide incentives for innovation (return of investment)
- Develop new knowledge and sharing (disclosure) → faster innovation lifecycles
- Improve agricultural productivity
  - Improving genetic gain
  - Improve sustainable increase in production
- Maximize socio-economic benefits
  - By improving genetic gain and farm productivity
  - Adding to the public domain of new knowledge and products to build upon and to continue further cycles of innovation

Without effective IPP

- Competitors free-ride or free-load
  - “Free riders” shoulder less than a fair share of R&PD
- A business cannot survive by funding competitors R&PD
  - By giving them technology
  - By giving them germplasm
  - By giving them trade secret information/know-how
- Cosmetic or plagiaristic “breeding” reduces genetic gain and increases crop vulnerability
- Undermine incentives to undertake long-term or risky R&PD when depend on ROI (private and some public sector)

With effective IPP

- Potential to recoup R&D investments
- Opportunity to reinvest in future R&D
- Multiple sites of innovation required
  - No single organization usually has all that is needed to develop a product
  - License during period of protection
  - In public domain-generic at expiration
- More likely to invest in risky or long-term development
  - New technologies
  - Access and make available a broader germplasm base

Funding for commercial plant breeding is highly correlated to availability of effective IP

- US Maize (hybrid); PVP, Patents widely used
  - Private sector breeding from the beginning and increased
  - Hybrids provide a level of IP
- US Soybean (self-pollinated) PVP, Patents widely used
  - Private sector breeding only after 1980 and increased
  - 1980 PVP Act, 1994 first soybean variety patented
- US Wheat (self-pollinated) PVP widely used, little patenting
  - Mostly public sector breeding
  - US PVP Act allows resowing without royalty
  - Relatively low rate of genetic gain

More IPP=More investment=Bigger Pie: Consumers and the seed sector benefit from stronger IP

NOT a zero-sum game!

Additional Discussion Topics

- Challenges with Patents
  - Patent thickets, Tragedy of the anticommons
  - Access to technology e.g. CRISPr Cas 9
  - Transparency-which varieties covered by which patents?
- Challenges with PVP
  - Level of protection decreases as technology facilitates access
  - Insufficient to encourage use of exotic germplasm
- Challenges with Trade Secrets
  - Maintaining them
  - Do not add much to social welfare as do not enter public domain and cannot license to others
- Interactions with other International Treaties
DuPont Pioneer and the Broad Institute of MIT and Harvard announced today that they have reached an agreement to jointly provide non-exclusive licenses to foundational CRISPR-Cas9 intellectual property under their respective control for use in commercial agricultural research and product development.

• Such foundational intellectual property (IP) for CRISPR-Cas9 technology will be freely available to universities and nonprofit organizations for academic research.

• (i) provides non-exclusive access to IP from Broad Institute co-owned with its collaborators (including Harvard University, the Massachusetts Institute of Technology, New York Genome Center, New York University, The Rockefeller University, and the University of Iowa), and

• (ii) provides non-exclusive access to foundational IP from Pioneer and to IP from the licenses that Pioneer gained access through Caribous Biosciences, ERS Genomics, and Vilnius University.
How to Protect Investment in Seeds?

TRIPS Article 27

1. Subject to the provisions of paragraphs 2 and 3, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application.
2. Members may exclude from patentability, the prevention within their territory of the commercial exploitation of which is necessary to protect order public or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law.
3. Members may also exclude from patentability:
   (a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals;
   (b) plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective sui generis system or by any combination thereof. The provisions of this subparagraph shall be reviewed four years after the date of entry into force of the WTO Agreement.

Increasingly genetic knowledge-based approaches
Unlocking Genetic Potential from the Wild
Steven D. Tanksley, Susan R. McCouch
Science August 22, 1997

Using phenotypic evaluation to determine the breeding value of an accession is likely to be misleading, especially with respect to quantitative traits.

We have been screening germplasm in a way that fails to expose its potential.

The paradigm needs to shift away from selecting potential parents on the basis of phenotype to evaluating them directly for the presence of useful genes.

Innovation through research to develop and deploy a more knowledge based approach:
Yield & Drought Tolerance: Genetic Gain for a Complex Trait

Germplasm:
- Genetic Variation for Drought Tolerance
- Phenotyping
  - High Throughput in the Target Environments
  - Genomics of Drought Tolerance in Elite Germplasm
- Iterative Model Building and Prediction
- Resources & Implementation

FROM MARK COOPER

Integrated Breeding System: Results of multiple innovations

PVP does NOT give to holder

- PROTECTION AGAINST FURTHER BREEDING
  - Other than from cosmetic or plagiaristic breeding via the EDV concept of UPOV 1991
    - Breeder has to police competitors

- FULL PROTECTION AGAINST FARMER RE-SEEDING
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EDV and Genetic Transformation

Initial protected variety

Transformed variety with essential characteristics of initial variety

Without EDV concept, developer of transformed variety captures all the ownership rights of the initial variety. Undermines future research incentives of first breeder.

Who are the beneficiaries of improved agricultural productivity?

Food Expenditures
Share of Disposable Personal Income
1929 - 2008

Without EDV concept, developer of transformed variety captures all the ownership rights of the initial variety. Undermines future research incentives of first breeder.

USDA uses public-private R&D partnerships to facilitate technology transfer

Active CRADAs
Active patent licensees [left axis]
Patent royalties [right axis]

Number
Constant 2007 US$ (millions)

Source: Data from 2001 are from Annual Reporting on Technology Transfer in USDA, Office of Science. Data before 2001 are from Hazen et al. (2001).

Plant breeding has become increasingly global: Route a new tomato variety might take before commercialisation