

Germplasm ownership, ethics, and value

Recommended reading:

'Patenting Agriculture'

Barton and Berger, 2001

Issues in Science and Technology Website

http://www.nap.edu/issues/17.4/p_barton.htm

What are the implications of intellectual property rights protection for plants and related technologies??

i.e., Who owns the worlds crop plants??

Goal for establishing intellectual property rights

Such as Utility patents, copyrights, PVP, etc.

1. **Create incentives** and stimulate new technological advances by providing **means and mechanisms to capture financial returns on investments.**
2. **Reward inventors** with exclusive rights for some period of time
3. Create avenue for **public disclosure of technology**, which provides stimulus for further advances.

Without stimulus and \$ returns provided by IPR protection, rate of technological innovation and advances would decline

Current principles and issues *at stake* in agriculture:

1 - Ownership of 'living organisms', genes, and resulting impact on international food security

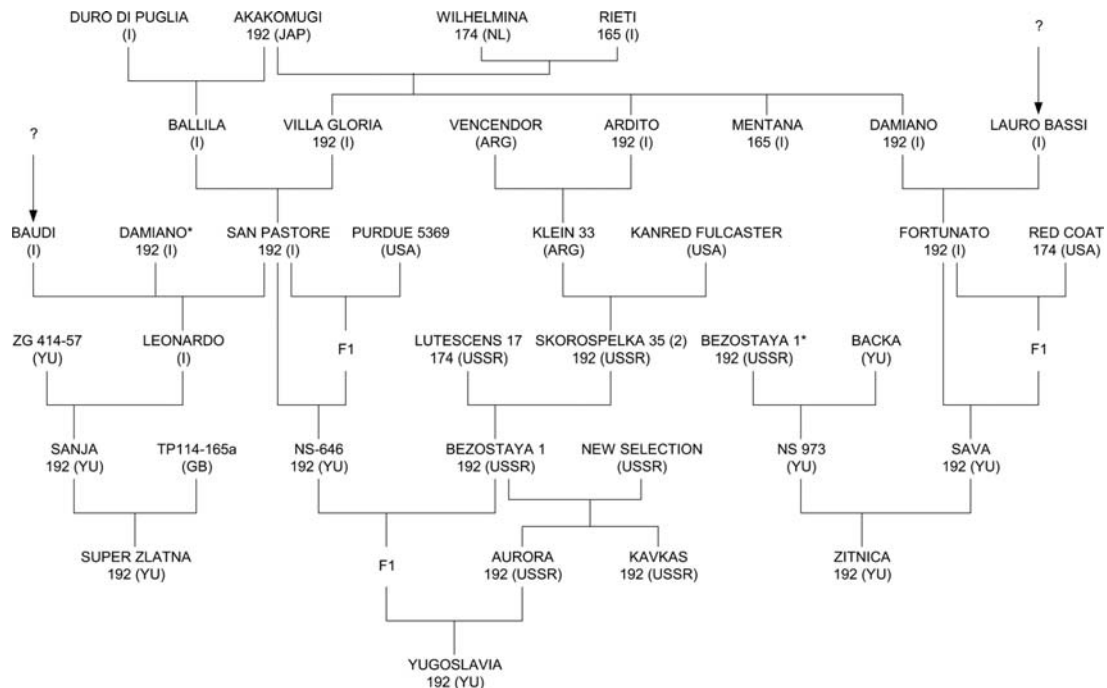
2 - Need for private companies to **recoup R&D investments**; but resulting in **increasing corporate control** over world food production.

3 - Impact on economic and social development of **developing countries**; concern over **access to agricultural technologies** by subsistence farmers and developing countries;

4 - Impact on **biological diversity**, genetic base of major crops, and long-term improvement efforts; concern over future of public research through USDA and Land-grant Institutions

Why is 'ownership' important:

Example: Lineage of Yugoslav wheat varieties



Free exchange of plant germplasm and information

**Hallmark of public U.S. Land-Grant Institutions
and International Research Centers;**

Foundation for modern plant breeding

Basis for Green Revolution – example of semidwarf gene- O.A. Vogel

Grants permission for use of germplasm:

in research under recipients control, and
as parent for making crosses without restrictions on progeny

Is free exchange of germplasm an ‘antiquated concept’??

Licenses and royalties are being sought by some Universities as means
to **generate revenue** as government support declines, restricting
access to germplasm

Exchange is increasingly **complicated by biotech patents** on single
genes, processes. Companies are increasingly restrictive, demanding.

A brief history of intellectual property rights - as related to plants and agriculture

<1930 Farmer’s rights

Farmers has direct access to seed and germplasm

Crops were ‘true breeding’ and **seed was easily saved**

Breeding was mostly publicly financed

Land-grant institutions established in 1860’s

***This discouraged private investments in plant breeding because of
difficulty in maintaining control over sales and markets and recouping
investments.***

1930's Trade secrecy

With introduction of hybrid corn, **saved seed was no longer** option due to **decline in heterosis** with selfing and **segregation for major traits**.

Hybrid varieties could then be **protected through trade secrecy**.

*Trade secrets and contracts are **often used as low-cost alternative** to more formal means of protection. **Breeders often will sequester segments of their program**.*

Proprietary corn hybrids were initially based on **public inbreds**; different names, brands; but same hybrid combinations.

Pressures to develop and support **commercial plant breeding** increased

Advantage: all released varieties and hybrids could be used as breeding materials

1930 Plant Patent Act - *first US legislation to protect plants*

Protection for **horticultural crops** and **nursery stocks**

Asexually propagated plants only

Plant reproduced through buds or grafting
- excluding potato

Variety must be '**distinct**' and '**new**'
(*already considered 'stable', as asexually propagated*)

Administered through US Patent Office.

1970 Plant Variety Protection Act (PVPA)

Goal was to **promote commercial investments in plant breeding**

Provides '**Patent-like**' protection for plants **reproduced by seed**.

Variety must be:

Distinct

Uniform

Stable

Novel in at least 1 trait

Establishes **Limited exclusive rights** to owners

Protection limited to **entire plant and harvested material**

Duration 20 years; cost currently ~\$3,500

Issued by USDA (less intensive review)

Seed sales only through '**authorized dealers**' (definition?)

Allows saved seed for use on farm, or for '**limited sale**'

Similar to 1961 European (UPOV) '**Plant breeders rights**' law
Breeders have right to exploit products of their profession
'Authorization' required for plant production, sale and marketing

'**Research exemption**' included for use of PVP varieties
in breeding

PVP continued:

Problems:

Widespread '**brown-bagging**' (illegal sales and use)

Erratic and **inadequate enforcement**

Enforcement responsibility of PVP holder

'Minor' penalties for violation or infringement

Concern over impact on germplasm exchange and crop diversity

Result:

***Increase in private breeding, but only for a few crops.** Market size and profit margins were primary determinants of commercial success. Crops such as wheat and barley, which are self-pollinated, faced with low profit margins for seed and extensive pirating, received only limited private investments.*

1980 Utility Patent of 'living organisms'

Diamond vs Charkrabarty **Supreme Court decision** – 1980

*Established '**anything under the sun made by man**' is patentable*

Broadens patent law to encompass living organisms

Establishes ownership of **plant varieties, traits, parts, and processes**

Claims can be broad based, including entire species

Examples: plant parts, seeds, cell cultures, plant tissues, transformed cells, expressed proteins, threshold traits, and genes themselves

Standards for issuance of Utility Patent:

*Must be **novel in relation to 'prior art'**;*

Useful;

***Non-obvious to one of 'ordinary skill in the art'**
(innovative step)*

Provides for more IPR protection than PVP, but at a higher cost, and with higher standard for issuance

Allows **complete prohibition of farm-saved seed**

Allows **prohibition of use in breeding**

Research exemption exists, but **not for any 'commercial use'**

Technology **license required to access, or save, seed**

Granted for **20 years**; application within 1 yr of 'disclosure'

Cost is 'considerable' (millions of \$'s)

First Utility Patent for GE Maize granted in 1985

*Chief interest in Utility Patents came from **inventors of biotechnology** products and processes.*

*Seed companies looked toward Utility Patents **for additional protection beyond that afforded by PVP.***

Photo: Corn borer, target for development and use of Bt maize varieties



1994 Amendment of PVPA / 1991 Revision of UPOV treaty

Eliminate 'saved-seed' and limit 'farmer's exemption' provisions

Farmer can save seed only for own on-farm replantings
(all unauthorized seed sales are prohibited)

Reaffirmed in Asgrow vs Winterboer, 1995 Court case

'Essentially derived' concept established to **expand breeders protection**

Violation loosely defined as '**intent**' to **recapture genotype** with 'minor modification'. Such as: mutants, somoclonal variants, backcrossing, genetic engineering. Definition TBD – *'in court'*

Brings PVPA into accordance with UPOV (EU Breeder's Rights)

Major International Agreements and Treaties on Plant Biodiversity

Controversies and challenges that impact conservation, exploration, access and use of plants, including access and use of crop germplasm and related species

Note what is often a very different perspective of developed vs developing countries, or gene-rich vs gene-poor countries, regarding management of genetic resources.

*Controversies over biodiversity generally involve **access, fair compensation, and adequate protection** for genetic resources, including unimproved plants, improved crops varieties, and novel genes.*

Conservation has been an immediate priority of the international research community, as 'once lost, lost forever'.....

1989 FAO - International Undertaking on Plant Genetic Resources

To ensure genetic resources will be explored, preserved, evaluated and made available for breeding and science

'Genetic resources are a heritage of humanity; should be available without restriction'

Established the **sovereign rights of nations** *to preserve, protect and be compensated for both access to, and for innovations utilizing their native genetic resources.*

Establishes '**Farmers' Rights**': *farmers should be compensated for development and conservation of genetic resources*

Challenge is to define reward: **who, how, how much??**
Non-binding international agreement

1992 Int. Convention on Biodiversity – Rio de Janeiro

Conservation of biological diversity established as an international priority

*Promote fair and equitable sharing of benefits from genetic resources. Maintain appropriate **access and transfer and protection** of relevant technology among countries.*

Reaffirms **sovereign rights of states** over natural resources, including genetic resources.

1994 TRIPS Agreement – Marrakech, Morocco

WTO members are obligated to provide/support patents for both products and process inventions in **all fields of technology**

Agree to **protect crops by adopting 'as low as standard of protection' as possible** – typically 'Plant Breeders Rights'

2001 - Plant Patenting *reaffirmed*

Supreme Court decision of December, 2001

JEM Agricultural Supply vs Pioneer Hybrid

Utility Patents, Plant Patents, and PVP are different, but 'complementary'

More vs less exacting requirements for protection

More vs less protection and ownership rights

Links for info on the Supreme Court decision:

The Brief:

http://supreme.usatoday.findlaw.com/supreme_court/briefs/99-1996/1999-1996.pet.ami.inv.pdf

Press releases: <http://www.bio.org/ip/agsupply.asp>

2004 - Canadian Supreme Court Ruling

In favor of Monsanto in case of Schmeiser vs Monsanto in biotech canola infringement.

Monsanto has right to patent gene and enforce its patent rights.

Impact on the future???

The Need to Revise Patent Law - *for Application to Crops* (from Barton and Berger, Issues, 2001)

Patents are **slowing innovations** in biotechnology

Difficulties and complexity of licenses
Significant risk of patent infringement

Allowances are needed for **food security** of **developing countries**

Grant open licenses and access to 'developing nations'
Provide public funding of licenses to developing countries
Non-discrimination in technology access: poor nations,
subsistence farmers

Need to increase difficulty to obtain Patents

Stronger standard for **rejecting the 'obvious'**
Narrow scope of patents
Permit **experimental use**; use in breeding

A Breeder's Perspective on IPR for plants (Sears and Cox, K-State and NWIC, 1994)

PVP is granted to variety as '**unique arrangement**' of genes

Protection should not be granted to 'pre-existing' genes

Allow others to use genes in new combinations

It is **appropriate to protect new or novel genes**

Don't use single gene to 'lock-up' entire genetic background

Analogy to IPR for books and language

Copyright for books as unique arrangement of words

Copyright not available for words that make up the book

Biotech addendum: new or novel words can be protected

Summary: US plant protection mechanisms

Plant Variety Protection Certificate:

Requirement: Novel in at least 1 characteristic from plants/varieties currently under PVP. Must be applied for less than 1 year after first commercial sale. Duration: 20 years; Cost: ~\$3,500

Seed sales through 'authorized dealers' only (definition varies). Farmer has right to 'save seed' for personal use.

Protection is limited to the entire plant itself and harvested material. To infringe, a plant must appropriate the variety characteristics recited in the certificate. Limited to claiming "a single taxon of the lowest known rank"

Issued by the U.S. Department of Agriculture after less-intensive review procedure. Subject to broad statutory experimental use exemption, which may shield researchers and potential competitors from infringement suits.

Utility Patent:

Property right that exclude others from making, using, offering for sale, selling the invention, or importing the invention; a 'limited monopoly'.

Duration: 20 years; Cost is 'considerable' compared to PVP.

Requirements: Novel in relation to 'prior art'; Not obvious to a person of ordinary skill in the art from prior art (at the time of invention). Must be applied for within 1 year of 'disclosure'.

Allows inventors to claim multiple parts of a plant and seed (e.g., recitation of genetic sequences; description of plant cells, cell culture and plant tissue; plants which are distinct in and of themselves. May be broadly used to claim multiple varieties or an entire genera or species of a plant.

Utility Patent, continued:

Issued after extensive review procedure by U.S. Patent and Trademark Office. Subject to limited, judicially created doctrine of experimental use, which protects users of the patented technology from infringement lawsuits only if their use is purely for research, and is not commercial.

Technology license required for anyone to access or sell seed. Farmer does not have 'right' to save seed for personal use.

Timeline for intellectual property rights

- 1865: Land-grant institutions formed to promote agricultural development Free and open exchange of information and germplasm**
- <1930: Farmers rights**
- 1930: Plant Patent for asexually reproduced plants**
- 1970: Plant Variety Protection Law – plant varieties reproduced by seed 'research exemption' for breeding purposes**
- 1980: Diamond vs Charkrabarty – first patent of 'living organism'**
- 1989/91 International Undertaking on PGR
Genetic resources as 'heritage'; farmers, nations have right to be compensated for access, utilization**
- 1991: Revision to UPOV treaty – limit farmers rights; 'essentially derived' concepts**
- 1992: Convention on Biodiversity**
- 1994: PVP amendment – farmer saved seed only for his own replanting**
- 1994: TRIPS agreement – obligation to provide patent protection**
- 2002: Supreme Court reaffirms use of Plant Patents**

Note: Oregon State University is in no way responsible for the content of this page. Any problems, discrepancies, or comments should be directed to the webmaster.

Last updated: 01/16/2008

**Copyright ©2002-08 Cereals Research
Department of Crop & Soil Science, Oregon State University, USA**

Contact [Webmaster](#)