

Intellectual Property Issues and Plant Biotechnology

Jim Myers
Department of Horticulture
Oregon State University

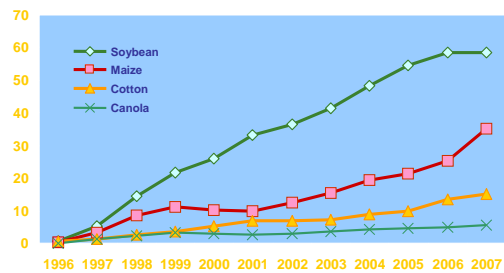
Traditionally, we shrink from permitting small, authoritarian minorities to dictate our social agenda, including what kinds of research are permissible and which technologies and products should be available in the marketplace.

Henry I. Miller, Hoover Institution, and Gregory Conko, Competitive Enterprise Institute (2001)
[Quoted in Kloppenburg, 2004. First the Seed]

Biotechnology: the predictions

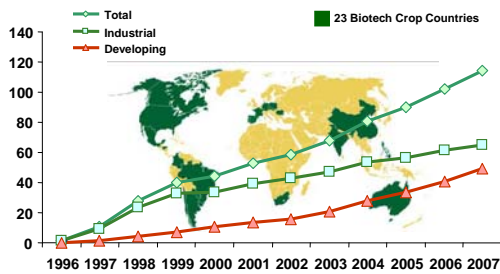
- Will revolutionize plant breeding
- A new "Gene" revolution
- Will feed the world's poor, hungry and nutritionally insecure
- Will make the crops easier and cheaper for farmers to grow
- Consumers will see plentiful food supply that is healthful, cheap and abundant
- The technologies are safe and non-controversial

Global Area of Biotech Crops, 1996 to 2007:
By Crop (Million Hectares)



Source: Clive James, 2008

GLOBAL AREA OF BIOTECH CROPS
Million Hectares (1996 to 2007)



Increase of 12%, 12.3 million hectares (30 million acres), between 2006 and 2007.
Source: Clive James, 2007.

Biotechnology: the reality

- Only 4 GMO crops (canola, cotton, maize, soybean) grown on significant acreages commercially
- >90% acreage in 5 countries (U.S., Brazil, Argentina, Canada, India)
- Two traits (herbicide & insect resistance) account for nearly all acreage
- Six companies (Adventis, Dow, Du Pont, Mitsui, Monsanto & Syngenta) control 98% of global biotech crop market

Biotechnology: the reality (II)

- Traits in commercial use benefit farmers in developed or graduated countries
- Global civil society debate over utility, safety, and ethics
- Only large multinational companies are able to commercialize GMO varieties
- Over half private sector agric. biotech patents obtained from 1982 - 2001 owned by Bayer, Dow, Du Pont, Monsanto, Syngenta

Outline

- Part I Commoditization of seed
 - Commons and anti-commons
 - Plant Patents
 - F₁ hybrids
 - Utility Patents
 - GURTs
- Part II Intellectual property applied to biotechnology
 - Utility patent primer
 - "Patent Thickets" and "Freedom to Operate"
 - Deconstruction of Golden Rice patent
- Part III Global treaties and agreements
 - TRIPS
 - CBD
 - ITPGRFA
- My recommendations for changes in IP

Part I Commoditization of seed

- Commons and anti-commons
- Plant Patents
- Plant Variety Protection
- F₁ hybrids
- Utility Patents
- GURTs

Closure of the genetic commons

- Seeds regarded as a public good for the past 10 millennia
- U.S. agriculture is based on introductions in the 19th & 20th centuries
- USDA collecting expeditions & government seed distribution programs
- Farmers saved their own seed & developed new varieties

Weak private sector but strong support for public agricultural research

- Morrill Acts of 1862 and 1890 established the land grant universities
- Hatch Act of 1888 established and funded the state agricultural experiment stations
- Smith Lever Act of 1913 established and funded the cooperative extension service

Scientific basis for plant breeding was established at beginning of 20th century

- Mendel's laws rediscovered
- Many public plant breeding programs initiated
- Public institutions became main source of new varieties

Seed companies sought less public competition

- Governmental seed distribution program was halted
- Lobbied for legislation to strengthen private enterprise in agricultural research
- Private sector could apply discoveries by public sector but needed an incentive
- Strengthened intellectual property protection
- Bayh-Dole Act (1980)
 - Requires Universities to commercialize their technologies

Intellectual Property protection for plants and seeds

- Plant Patent (1930)
 - Asexually propagated crops (except potatoes)
- Plant Variety Protection (1970)
 - Seed propagated crops (& potatoes)
 - UPOV implemented in U.S. in 1994 (global harmonization)
- Utility Patents (first utility patent granted 1790)
 - Diamond vs. Chakrabatry (1980 – microorganisms)
 - Ex parte Hibberd (1985 – USPTO extended to plants)
 - Pioneer vs. J.E.M. (Supreme Court affirmed application to plants)

Trend has been towards an increasing commoditization of seed over time

- F₁ Hybrids
- IP protection
 - Plant patents
 - PVP
 - Utility patents
- Gene Use Regulation Technologies (GURTs)
 - “Terminator technology”
 - Owner controls seed viability

Impact on plant breeding and biotechnology research

- Data, germplasm & technology sharing restricted
- Varieties released with IP constraints
- Globally:
 - Developing countries prohibit germplasm collection & exchange
 - IARCs restrict germplasm access
- Public institutions lack the resources to commercialize transgenic varieties
- A small minority of multinational corporations now controls significant production of several of our staple crops

Part II Intellectual property applied to biotechnology

What is Intellectual Property?

- Technologies
 - Plant varieties
 - Gene sequences
 - Plant secondary products
- Designs
- Processes
 - Transformation
 - Marker assisted selection

PVP vs. Utility patents

Provision	PVP	Utility
Breeder's exemption	Yes	No
Permits essentially derived	No	Yes
Farmer's exemption	Yes (narrowed under UPOV)	No
Scope	Cultivars only	Any technology or method
Requirements	Distinct – Uniform – Stable	Novel – Useful – Non obvious – Prior art

PATENT LAW PRIMER

• **In exchange for a limited monopoly, you must publicly disclose how to make the invention**

• WHAT A PATENT IS

- the right to prevent others from making, using, or selling your invention, or offering it for sale

• WHAT A PATENT IS NOT

- does not give you the right to practice your invention
- for instance, you are not free to practice your invention if it cannot be done without infringing someone else's intellectual property rights

Mary Foley, Tech. Transf. Office, OSU

WHAT IS PATENTABLE?

- Useful
- New
 - before your invention it was not publicly known or used by others in the United States;
 - before your invention it was not described in a patent or other printed publication anywhere in the world
- Non-obvious
 - at the time of your creation, your invention was not obvious to others in your field, called "persons of ordinary skill in the art"
- Filed by the Inventor

Mary Foley, Tech. Transf. Office, OSU

WHEN TO APPLY? WHAT IS ON-TIME?

- Timing is important
 - Invention not patentable until working form of the invention has been conceived in the mind of the inventor(s)
 - Not necessary that the invention actually be made or tested
- U.S. application must be filed within one year after the invention is first described in any publication world-wide, or placed on sale, sold, or used publicly in the U.S.
- Exceptions – legitimate experimental use to perfect or develop the invention

Mary Foley, Tech. Transf. Office, OSU

PARTS OF A UTILITY PATENT

- Specification
- Drawings
- Claims
 - the claims describe the scope of protection

Mary Foley, Tech. Transf. Office, OSU

THE THREE PARTS OF A CLAIM

- PREAMBLE
 - Identifies the category of the invention (i.e. apparatus, article, composition, or process). May recite the intended use
- TRANSITIONAL PHRASE
 - Connects the preamble to the body of the claim. E.g. comprising, consisting of, consisting essentially of.
- BODY
 - List of interrelated elements, e.g. components, ingredients, steps.

Mary Foley, Tech. Transf. Office, OSU

“Reading” A Claim (cont.)

- If translational word is “comprising,” claim with elements A, B and C reads on prior art with elements A, B, C and D.
- If translational word is “consisting of,” claim with elements A, B, and C does not read on prior art with elements A, B, C and D.
- If translational word is “consisting essentially of,” claim with elements A, B and C may read on the prior art with elements A, B, C and D as long as D does not enhance or interfere with elements A, B and C.

Mary Foley, Tech. Transf. Office, OSU

Do patents on plant biotechnology meet criteria?

(Novel – Useful – Non obvious – Prior art)

- Novel – yes and no (examples of both)
- Useful – yes and no (can't patent DNA sequence w/o knowing usefulness)
- Non-obvious – ? (rigor established by patent examiner)
- Prior art identified? – yes and no
 - Inventors and patent examiners to not always hold to a high standard for searching the prior art

Utility patents

- On plant technologies can be quite broad and grant monopolies that interfere with development of varieties using that trait
- For variety protection – is a dubious fit to non obviousness

Categories of utility patents

- Products *per se*
 - DNA sequence useful for synthesis of carotenoids
- Products-by-process
 - Enhanced regeneration system applied to cereals
- Uses
 - Use of pro-vitamin A to mitigate disease
- Processes (technical procedures)
 - Method of transforming monocots

Examples of problematic patents

- Co-opting germplasm in the public domain
 - Mayocoba (yellow beans) (5,894,079)
 - Basmati rice (5,663,484)
 - Late blight resistance in tomato (5,866,764)
- Fails non-obvious test
 - Popping beans (6,040,503; 6,419,976)

Patenting in self defense

- Multiple disease resistant cucumber (20040055033; 20040055034)

Breadth of patents

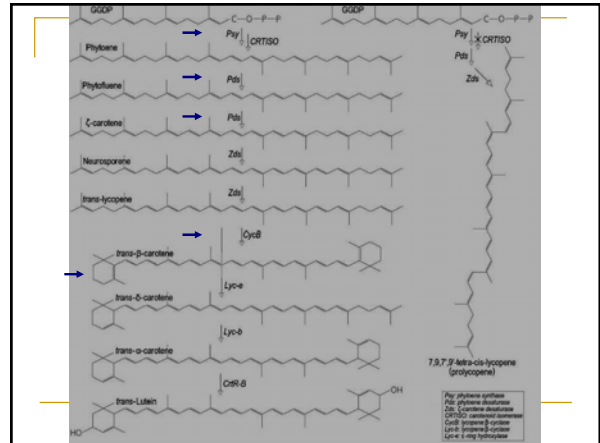
- Patent lawyers try to obtain as broad claims as possible
- Patent examiners generally limit these but sometimes not
 - Have limited time to review a patent
 - Often not experts in the field of the patent
- Examples of broad patents:
 - Tomato flavonoids
 - Popping beans

The Patent Thicket

- As patents and MTAs multiply, complexity increases exponentially!
- Creating an anti-commons – numerous IP claims to separate elements required to pursue research & product development
- Patent holders restricting access to upstream discoveries
- Cost – a barrier to becoming a player
- Patenting strategies:
 - Patent clustering (interlocking patents on different components of a product)
 - Patent bracketing (patent clustering around a competitor's patent)

Deconstructing Golden Rice IP thicket

- A rice variety engineered to produce beta-carotene
- Very complex project
 - Required introduction of 3 structural genes in the carotenoid pathway
- Will it be effective?
- The intellectual property (IP) component alone is daunting!

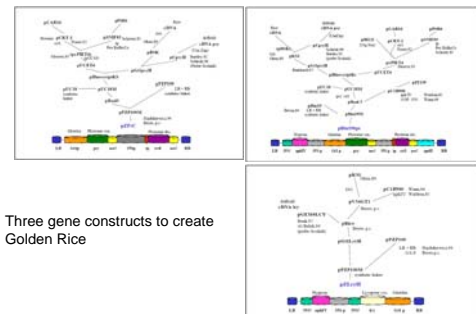


Freedom to Operate Analysis

- A risk management opinion
 - Dynamic and not a definitive answer
- Routinely used by corporations to analyze the IP landscape for a new product
- Review of IP and TP (technical property)
- Information to develop strategic deployment plan
- Advice on how to manage IP/TP constraints

Kryder et al., 2000. The intellectual and technical property components of pro-vitamin A rice (GoldenRice): A preliminary freedom-to-operate review. ISAAA Briefs No. 20. ISAAA:Itasca 56p. (www.isaaa.org)

Flow chart of tangible property transfers



Three gene constructs to create Golden Rice

5) Regeneration		
Regeneration of rice	US5350688	Method for regeneration of rice plants
	WO9419930	Enhanced regeneration system for cereals
6) Molecular techniques		
PCR technique	US4683202 US4683195 US4965188 EP0509612 EP0502588 EP0502589	Process for amplifying nucleic acid sequences
Taq polymerase	US4889818 EP0258017	Purified thermostable enzyme and process for amplifying detecting, and/or cloning nucleic acid sequences using said enzyme

MTAs, Licenses, Documents and Agreements Relevant to Golden Rice

Product Component	Source of component
1. Rice germplasm transformed with gene construct(s)	Taipei 309, obtained from IRR1
2. PGEN44	Promega
3. PbluescriptKS	Stratagene
4. pCIB900	Ciba-Geigy Limited (now Novartis Seeds AG)
5. Camv35S Promoter (component of pCIB900)	Monsanto
6. Camv35S Terminator (component of pCIB900)	Monsanto
7. AphIV gene: hygromycin Phosphotransferase (component of pCIB900)	Ciba-Geigy Limited (now Novartis Seeds AG)
8. PKSP-1	Thomas Okita, Washington State University
9. GT1 Promoter: glutelin storage protein (component of pKSP-1)	Thomas Okita, Washington State University
10. pUCET4	N. Misawa, Kirin Brewery Co., Ltd.
11. Pea Rubisco transit peptide (component of pUCET4)	N. Misawa, Kirin Brewery Co., Ltd
12. CrtI gene: phytoene desaturase (component of pUCET4)	N. Misawa, Kirin Brewery Co., Ltd
13. PP2P100	Pal Maliga, Rutgers University
14. pYIPET4	Clontech, but now marketed by Life Technologies
15. Electroporation Apparatus	Bio-Rad Corp., Gene Pulser II System
16. Microprojectile Bombardment Apparatus	Bio-Rad Corp.

The numbers:

- 15 Technical property components (MTAs)
- About 70 patents overall (not all apply in all countries)
- 44 patents in US; 40 in EU
- Negotiations with 12 – 20 entities

Fewer patents in developing countries

- China (10)
- India (5)
- Indonesia (6)
- Bangladesh (0)
- Vietnam (9)
- Thailand (0)
- Myanmar (0)
- Japan (21)

- Process patents:
 - Claims cover process only in country where patent is issued.
- Export considerations:
 - Must negotiate license for product patents even if not covered in country of development – if product is exported to country with patent

IP management strategies

- Invent around current patents
- Re-design constructs
- IP/TP owners relinquish claims
 - (Zeneca & Monsanto already have)
- Ignore all IP and TP claims
- Seek licenses on all IP and TP
- Mix of all options

Golden Rice wrap-up

- Negotiations nearly complete
- Some major IP holders have donated licenses
- Progress made in introducing into adapted varieties & increasing expression levels
- No safety tests yet
- 3 years (?) until introduction into farmers' fields
- IRRI scientists have discovered naturally occurring rice with beta-carotene in the grain
- Which will come onto the market first?

“...FTO opinion, including the information presented in this report:”

- “Varies on a country-by-country basis because most statutory protection is founded in national law, and patents are issued by national governments;
- Is dynamic because patent status is dynamic (new patents are issued or expire daily, sold or licensed, disputed or rendered invalid by courts. therefore ownership changes, and the impact of specific claims are constantly changing); and
- Is always an opinion and never a definitive answer.”

New business opportunities!

- Brokering patents
- Patent portfolios are becoming very important assets to corporations
- Very fluid business
- Some companies derive primary support from managing their patent portfolio

Patent issues

- When first issued in a new area, utility patents tend to be overly broad
 - Patent examiner needs access to relevant prior art (database of the gray literature)
 - USPTO draw on research community through non-disclosure contracts
- Patents are being used to claim germplasm in the public domain

Patent issues (II)

“...if today’s intellectual property practice had been in place 30 years ago, then it would be very unlikely that US corn yields would have reached today’s level.” –Gouache (2004)

- Creating restricted-access genetic populations
 - Two tiers: public domain unimproved & proprietary elite
- Restricted germplasm exchange
 - Esp. developing countries
- Reduced rate of genetic improvement
 - Cannot cross with just anyone’s material

Part III Global treaties and agreements

International consequences of intellectual property rights

“In an uncertain farmer’s rights environment, the traditional exchange of genetic materials could be curtailed.” –Everson (1999)

- Access to germplasm from some developing countries restricted due to perceived imbalance
 - Germplasm obtained for free from developing countries; germplasm in modified form sold back to them with unfavorable trade agreements imposed
 - Trade-Related Aspects of Intellectual Property Rights
 - Convention on Biological Diversity
 - International Treaty on Plant Genetic Resources for Food and Agriculture

International Treaty on Plant Genetic Resources for Food and Agriculture

- Establishes a Standard Material Transfer Agreement
- Provides for remuneration if germplasm is used to develop commercial product
- But...
 - Early germplasm collections not grandfathered in
 - Certain crops excluded for political reasons

Changes in UPOV

GRAIN briefing

February 2007

The end of farm-saved seed?

Industry's wish list for the next revision of UPOV



- European businesses want to eliminate farmers' exemption
- American corporations want to eliminate the breeders' exemption
- PVP will become a weaker version of Utility patents

The big debate in the UPOV process is whether to grandfather existing plant varieties into the plant variety protection system, which was the alternative to patenting that they set out in the 1990s. The European want to get rid of farmers' breeders' exemption to save seed. The Americans want to reduce the exemption to which breeders have the free use of each other's commercial varieties for research purposes. In both cases, the goal is to reduce competition and lower profits. In the short term, the rules will be loosened, who will probably end up being the seed giant as well as the UPOV holder. In the long run, we will all lose from the growing power of intellectual property on plant varieties. The bottom line is the overall movement away from the public domain and towards what will happen if a plant variety right becomes virtually unchallengeable from a patent.

Recommendations for changes in IP

- Prohibit patenting of public domain germplasm & varieties
- Allow limited research exemption in utility patents
 - Freedom to operate for the public sector to further scientific knowledge
 - Conditionally exempt traits that are in the interest of national food security
- Allow a modified breeders exemption (5 yr moratorium)
- Variety and trait patents should be limited in scope
- Patent examiners should establish a peer reviewer system
- Raise the bar of novelty, non obvious, prior art criteria

"...patent system has come to be increasing about protecting investment rather than promoting innovation..."

"...the loosening of the definition of 'utility', the way inventive step and novelty are applied in patent applications, and an apparent willingness to leave it to the courts to decide the validity of patents are bring the system into disrepute. Some see a risk of the US system turning into a patent application registration system as opposed to a patent granting one."

"Since crop genetic improvement is a derivative process, each incremental improvement made through biotechnology now comes with a number of IP constraints, with new IP added with each ... further improvement."

Future Control of Food

"...when there is a shift in R & D to the private sector, 'relying on the private sector for agricultural research is likely to result in under investment from the point of view of society.' Basically, it will not work on things for poor farmers, who have no money, nor on things that can be freely copied and given away."

Joseph Stiglitz, former World Bank chief economist
[quoted in Future Control of Food]

Points to ponder:

- As an end user, what rights should you have to patented material?
- As a researcher how should you be allowed to use patented plant germplasm?
- How do we increase rigor at the patent office?
- How do we prevent patent thickets?
- How do we create a workable system to compensate the originators of technical property (germplasm) in developing countries?
- Has the IP system created a "science anti-commons?"
- For anyone doing research: Who owns your work?