Intellectual Property Access for Agricultural Research and Commercialization

Gregory D. Graff, PhD
Research Economist, Public Intellectual Property Resource for Agriculture
Visiting Postdoctoral Researcher, Ag. & Resource Economics, UC Berkeley
Introduction: The role of publicly funded research for agriculture

“It shall be the object and duty of the State agricultural experiment stations ... to conduct original and other researches, investigations, and experiments ... contributing to the establishment .. of an ... effective agricultural industry of the United States and for the ... maximum contribution by agriculture to the welfare of the consumer”

Morrill Act, 1862
Hatch Act, 1887, amended 1955
United States Congress
Agricultural research – historically a public good for developing world
Agricultural research – historically a public good for regional crops, small market and specialty crops
The Times, They Are a Changin’:  
Broad trends in public sector

- Post-WWII expansion of government-funded civilian research:
  
<table>
<thead>
<tr>
<th></th>
<th>1990</th>
<th>2002</th>
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<tbody>
<tr>
<td>USDA</td>
<td>$ 1.21 B</td>
<td>$ 1.91 B</td>
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<tr>
<td>NSF</td>
<td>1.73 B</td>
<td>3.26 B</td>
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<tr>
<td>NIH</td>
<td>8.52 B</td>
<td>24.23 B</td>
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- Diamond v. Chakrabarty, 1980
- Pioneer v. JEM Ag Supply, 1994

- Bayh-Dole Act, 1980

- Growth of a research intensive biotech industry (=demand for university output)
Why should the public sector get involved in patenting inventions?

• Patents are a “deal” with the government to provide a period (20 years) of exclusivity in exchange for publishing the new knowledge (invention).

• The exclusivity provided by patents is important to encourage additional R&D investment in early stage inventions, to drive entrepreneurship and to create new products for the public benefit.

• Without patents – company’s rely on trade secrets and public-sector inventions languish in the “public domain”.

• Intangible property now represents over 70% of the value of technology-based companies and as much as 50% of total annual capital investments by publicly traded U.S. companies.
Areas of invention disclosure in University of California’s agricultural research
Universities are an important source of innovation... ...and patents help

- University of California inventions launched the biotechnology industry *(Cohen & Boyer, 1973)*
- 1 in 3 biotech companies located within 35 miles of a UC campus
- 1 in 4 biotech companies founded by UC faculty
But problems have arisen: the anticommons

The Tragedy of the Commons
1968
Garrett Hardin

Can Patents Deter Innovation? The Anticommons in Biomedical Research
1998
Michael A. Heller and Rebecca S. Eisenberg

- High transaction costs of negotiating multiple licenses – even if possible
- Stacking – license fees may exceed profit from research

for the greatest number” be realized?
No—for two reasons, each sufficient by itself. The first is a theoretical one. It is not mathematically possible to maximize for two (or more) variables at the same time. This was clearly stated by von Neumann and Morgenstern (3), but the principle is implicit.
Needs for coordination of multiple complementary technologies

- **Traits**
  - Disease/Stress resistance
  - Nutritional enhancement
  - Stress (salt/drought) tolerance

- **Enabling Technologies**
  - Vectors
  - Promoters
  - Selectable markers

- **Germplasm**
Anticommmons wakeup call: Golden Rice

70 proprietary technologies; 40 US patents

• Uncertainty
• High transaction costs

“Golden”
Problems that have arisen: bottlenecks

– 58% of researchers surveyed at UC Berkeley, UC Davis, UC Riverside, and University of Arizona have experienced research impeded by proprietary research tools (Lei and Wright, 2005).

– U.S. Supreme Court case *Mady v. Duke* emphasizes that even fundamental research may be blocked by IPRs; further erodes already dubious “research exemption”.

– New technologies continue to arise at public sector institutions, but drop in numbers of new agbiotech startups since mid 1990s.

– Access to key enabling technologies for transformation blocks development of transgenic crops for humanitarian uses. Selectable marker technology is licensed to CGIAR for “research use” – but CG researchers cannot distribute crops produced using this technology.
Problems that have arisen: uncertainty

Example: *Agrobacterium* plant transformation

- Dozens of patents issued (Rao-Rodriguez & Nottenberg, 2001; Pray & Naseem, 2005; Graff, 2005)

- European patent filings issued in early 1980s, already expired.

- US patent filings of Monsanto and Max Plank went into interference at USPTO in early 1980s
  - Settled in late 2004
  - Likely to issue in 2006
  - Patent application (claims) still not published
  - Keeping everyone in limbo on questions of FTO in agrobacterium
Problems that have arisen: uncertainty

Bacterial blight resistance in rice - XA21

• Royalty-free license
• Genetic resource fellowship fund

BUT…

• Three years of negotiation
• Restricted germplasm/gene exchange

Philippines' Blight-Resistant Rice Scheduled for Field Trials
"Biotech Rice To Be Tested in Nueva Ecija, Laguna," Philippine Daily Inquirer
These are problems for universities, government agencies, not-for-profit agricultural research institutions and private companies.

What are the options?
How can public researchers contribute to the solutions and fulfill their historical role in technology development for “orphan” and subsistence commodities in this IP environment?

- Specialty crops
- Low commercial value traits – human nutritional amplification
- Public-sector/university plant breeders

- Traits targeted to subsistence farmers
1. **Inventory of public sector patented technologies in agricultural biotechnology**

2. Case studies – using public sector IP to achieve freedom to operate in Agricultural Biotechnology

3. A collaborative, public IP management organization
Annual PCT filings of plant biotechnologies 1984-2000

(total: 3393 filings)

- Private Sector
- Uncertain
- Public Sector
Private Sector – 97.3%

Public Sector – 2.7%

All technology areas - USPTO

Agricultural biotechnology

- Monsanto: 14%
- Du Pont: 13%
- Syngenta: 7%
- Bayer: 4%
- Dow: 3%
- Rest of private sector: 33%
- Unknown: 2%
- Public sector: 24%

Graff et al, Nature Biotech, 2003
Germplasm

Enabling Technologies

Genetic Traits

Tissue culture Technologies

- Soybean Cultivar
- Inbred Corn
- Seed
- Plant Breeding
- Resistance Pathogens
- Herbicide Resistance
- Degrading Enzymes
- Nucleic Acid Polypeptide
- Nucleic Acid Fatty Acids
- Resistance Rice Fungus
- Enzyme Chitinase
- Plant Enzyme
- Protein
- Strain DNA
- DNA Nucleotide Sequence
- Plasmid Vector
- Grain Starch
- Bacillus Toxin
- Protoplasts particles
- Plant Callus Growth
- Differentiate Culture
- Embryos Somatic
- DNA Cultures
- Male Sterile Seeds
- Promoters
- Regulatory Elements
- Virus Protein
- Fruit Promoter
- 10%
- 42%
- 25%
- 57%
Our own anti-commons

“Our own anti-commons”
Inventory of the IP Landscape for Promoters

**Constitutive:**
1. FMV 34S promoter (University of California)
2. Mannopine/nopaline/octopine synthase (Purdue University)
3. FMV and PCLVS FLt promoter (University of Kentucky)

Also:
- Root specific
- Seed specific
- Inducible
- etc.
1. Inventory of public sector patented technologies in agricultural biotechnology

2. Case studies – using public sector IP to achieve freedom to operate in Agricultural Biotechnology

3. A collaborative, public IP management organization
The impact of public-sector research is evident in many technology sectors, and this is particularly true in agriculture. Dating back to the establishment of the Land Grant College system in 1862, universities and other public-sector institutions have been the leaders in developing improved crop varieties that were transferred to farms and to the agricultural industry through cooperative extension services in the United States or equivalent organizations internationally. However, this model is changing rapidly because of increased intellectual property (IP) protection. (3) However, these practices are not universally applied across institutions, with the result that, although many significant discoveries and technologies have been generated with public funding, these discoveries are no longer accessible as “public goods.”

Our institutions have found that the public research sector finds itself increasingly restricted when wishing to develop new crops with the technologies it has itself invented, including so-called “enabling technologies”—the research tools necessary for further experimentation and innovation. In agricultural research, applied research and genetic improvement of crops are derivative processes based on pre-existing plant material, and each incremental improvement now brings with it a number of IP and germplasm constraints that have accumulated in the plant material. When IP rights for agricultural materials and technologies are held by multiple public-sector owners,
PIPRA’s Vision

To strategically manage the present and future public intellectual property estate in the agricultural life sciences to promote access to members’ technologies for research purposes, to enable their widest possible development and commercial adoption in specialty crops, and enable their widest possible use in crops for humanitarian purposes in the developing world.
Who is PIPRA?

*Arizona State University
*Boyce Thompson Institute for Plant Research
*Cornell University
*Donald Danforth Plant Science Center
*Iowa State University
*North Carolina State University
*Samuel Roberts Nobel Foundation
*Salk Institute

*University of Arizona
*University of California, Davis
*University of California, Berkeley
*University of Arkansas
*University of Missouri, Columbia
*Washington State University
*University of Wisconsin

Michigan State University
Louisiana State University

Purdue University
Ohio State University
Yale University
University of Florida
University of Kentucky
University of Georgia
Rutgers University
University of Hawaii
Kansas State University
CIMMYT
IRRI
Parco Technologico Padano
PIPRA’s Goals

Increased awareness of IP and FTO issues in public sector agricultural research.

Better collaborative management of public sector institutions’ IP assets.

Provision of tools with maximal FTO for public research.

Enablement of projects targeted toward
- regional mandates for agricultural R&D and
- global food security.
We are implementing this vision through PIPRA’s four areas of service:

- Information & analysis
- Educational services & outreach
- Laboratory research activities
- Collaborative management of IP
PIPRA’s potential clientele:

- Public / non-profit research institutions
- In developed countries
- In developing countries
- Research sponsors
- Commercial partners
<table>
<thead>
<tr>
<th>Area</th>
<th>Possible Services</th>
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<tbody>
<tr>
<td></td>
<td><strong>Database of PIPRA members' IP holdings</strong></td>
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</table>
|      | **FTO analysis services:**  
|      | Evaluation of IP around a *specific* technology |
|      | *Landscapes*: art and literature assessment |
|      | *Opinions*: legal analysis of claims |
|      | **Technology IP overviews:**  
|      | Evaluation of *all* IP in a broad technology sector |
|      | **Strategic portfolio analysis:**  
|      | Evaluation of IP position of particular institutions |
|      | **Industry level analyses** *(ex: R&D pipeline project)* |
|      | **Policy and regulatory analyses** |
|      | **Development/ sharing of supporting datasets** |
|      | **etc...** |
Numbers of records, by reporting member:

- University of California (UC) 887
- North Carolina State University (NCSU) 45
- Iowa State University (ISU) 45
- Boyce Thompson Institute for Plant Research (BTI) 24
- Cornell University 308
- University of Florida (UFL) 46
- University of Wisconsin (WARF) 52
- Purdue University 128
- Washington State University (WSU) 290

Total: 1868

Submission of data by new members is in progress
Total Number of Records
1868
Search by Licensing Status

26 search fields
### Patent lifetime before expiration date

<table>
<thead>
<tr>
<th>Patent</th>
<th>Title Assignee</th>
<th>Classification</th>
<th>Filed Issued</th>
</tr>
</thead>
<tbody>
<tr>
<td>US655,9357</td>
<td>Methods for altering mass and fertility in plants</td>
<td>800/290 MULTICELLULAR LIVING ORGANISMS AND UNMODIFIED PARTS THEREOF AND RELATED PROCESSES</td>
<td>08-JAN-1999 06-MAY-2003</td>
</tr>
<tr>
<td>US651,1621</td>
<td>Methods and compositions for production of floral scent compounds</td>
<td>435/69.1 CHEMISTRY: MOLECULAR BIOLOGY AND MICROBIOLOGY</td>
<td>01-SEP-2000 06-MAY-2003</td>
</tr>
<tr>
<td>US650,1007</td>
<td>Maize endo-1,3;1,4-glucanase nucleic acid</td>
<td>800/298 MULTICELLULAR LIVING ORGANISMS AND UNMODIFIED PARTS THEREOF AND RELATED PROCESSES</td>
<td>09-JUN-1999 31-DEC-2002</td>
</tr>
<tr>
<td>US650,0906</td>
<td>Nucleic acids conferring chilling tolerance</td>
<td>800/289 MULTICELLULAR LIVING ORGANISMS AND UNMODIFIED PARTS THEREOF AND RELATED PROCESSES</td>
<td>08-NOV-1999 01-FEB-2000</td>
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### Licensing Information

- **Licensing Information**

  - [Licensing Information](#)
Direct Link to PIPRA or member’s OTT
PIPRA’s Access to M-CAM’s Analysis Tools

Patent surrounding US5432068

- Patents processed concurrently with the technology of interest (potential licensees)
- Assignees working in overlapping technology space (potential licensees)
- Possibly uncited prior art (potential licensees)
- Cited Prior Art Patents
- Subsequent patents that cited this patent
Assignees with similar technologies: Potential licensees
<table>
<thead>
<tr>
<th>Area</th>
<th>Possible Services</th>
<th>Public/Non-Profit Research Institutions</th>
<th>Research Sponsors</th>
<th>Commercial Partners</th>
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<td>Developed</td>
<td>Developing</td>
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<tr>
<td>Educational services &amp; outreach</td>
<td>PIPRA presentations</td>
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<td></td>
<td>Publications (ex: licensing handbook, FTO/industry/policy analyses as working papers)</td>
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<td>Professional training/ seminars/ courses</td>
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<td>Advising/ consulting</td>
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<td>Answering IP and FTO FAQs (ex: webpage, 'hotline', blog, listserv, etc.)</td>
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<td>Website, newsletter, brochure, prospectus, annual reports</td>
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• Advocating best practices to support broad innovation potential:
  - differentiation of specific fields of use in licensing terms (crop, region)
  - explicit reservation of rights for “humanitarian use”

• Definitions:
  “Humanitarian Purposes” means (a) the use of Invention/Germplasm for research
  and development purposes by any not-for-profit organization anywhere in the
  World that has the express purpose of developing plant materials and varieties for
  use in a Developing Country……..

• Reservation of rights. “Notwithstanding other provision of rights granted under
  this agreement, University hereby reserves an irrevocable, non-exclusive right in
  the Invention/Germplasm for Humanitarian Purposes. Such Humanitarian
  Purposes shall expressly exclude the right for the not-for-profit organization
  and/or the Developing Country, or any individual or organization therein, to export
  or sell the Germplasm, seed, propagation materials or crops from the Developing
  Country into a market ….. where a commercial licensee has introduced or will
  introduce a product embodying the Invention/Germplasm……..
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<td>Developed</td>
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<tr>
<td>Laboratory research activities</td>
<td>Technical evaluation and characterization of research tools:</td>
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<td></td>
<td>Plant transformation vectors</td>
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<td>Promoters</td>
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<td>Selection systems and markers</td>
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<td>etc...</td>
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<td></td>
<td>Collaborative design and development of new research tools (ex: vector workshop/project)</td>
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<td>etc...</td>
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**Laboratory activities:** supporting FTO analyses and pPIPRA vector design

- Providing patent landscape information and paths toward FTO for specific technologies: promoters, markers, etc.

Network of *pro bono* attorneys advising PIPRA

- Redesigning enabling technologies around PIPRA owned components

Plan to distribute transformation vectors with maximal FTO, free for research humanitarian uses, and predefined licensing terms if used in a crop that is commercialized (Cohen-Boyer model)
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<td>Joint marketing</td>
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<td>Out-licensing</td>
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<td></td>
<td>- Adopting common practices in licenses (humanitarian-use/fields-of-use)</td>
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<td></td>
<td>- Multi-component, multi-technology licensing (pooling)</td>
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<td>Negotiating access</td>
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<td></td>
<td>- Assist members and clients in negotiating with outside IP owners</td>
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<td></td>
<td>- Common MTA</td>
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<td>Facilitate public-private research collaborations (ex: Pierce's disease consortium)</td>
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<td>etc...</td>
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<tr>
<td>Collaborative management of IP</td>
<td>Public/Non-Profit Research Institutions</td>
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<td>Developed</td>
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Collaborative IP Management: *Tactical thinking*

- Analyze public sector agricultural IP as a single portfolio
- Identify strengths & weaknesses
- Bundle technologies for commercial or humanitarian licensing
- Reduce transaction costs for licensees
- Cross-license with private sector
Develop & license shared technology packages

US public sector research institutions + others?

Ag-bio IP clearinghouse: PIPRA
Broker for minor/subsistence crop applications
Assemble “virtual” patent pools

License components or aggregate

Data and IP

Humanitarian use license
Subsistence farmers

Commercial license
Small market crops

public intellectual property resource for agriculture
Collaborations…

• Internationally
  • Managing IP for Health Research (MIHR)
  • African Agricultural Technology Foundation (AATF)

• Legal community
  • PIIPA

• Educationally
  • Franklin Pierce Law School
  • Washington University Law School
  • Center for Intellectual Property Studies, Chalmers University

• Regulatory
  • Specialty Crop Regulatory Initiative (SCRI)

• Funding groups
  • Rockefeller Foundation
  • McKnight Foundation
  • Pierces Disease Board/Vineyard Foundation
  • Institute for Forest Biotechnology
CONCLUSION...

• PIPRA is a unique initiative that offers a solution to complex IP related issues
• PIPRA is laying the groundwork for the future – to make sure innovations remain available for a wide range of commercial and humanitarian uses
• Membership is open to agricultural research institutions - contact us for more info
• As of July 2004, PIPRA has been based in Davis, CA
EXECUTIVE COMMITTEE

Karel Schubert, Danforth Center
Lisa Lorenzen, Iowa State University
Henry Lowendorf, Yale University
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Gerard Barry, IRRI
Carlos Fernandez, Fundacion Chile

UC DAVIS

Alan Bennett
Sara Boettiger
Cecilia Chiham
Gregory Graff

For more information:

www.pipra.org

THANK YOU