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IPRs, FTO, and Alternative Structures for Agricultural R&D

Gregory D. Graff

PIPRA

University of California, Davis

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Key topics

- R&D in the knowledge economy
- Intellectual property rights
- Freedom to operate
- The market for IPRs
- Impacts on agricultural biotechnology R&D
- Alternative structures
  - Public-Private Product Development Partnerships
  - Open Source
  - Patent Pools
- PIPRA

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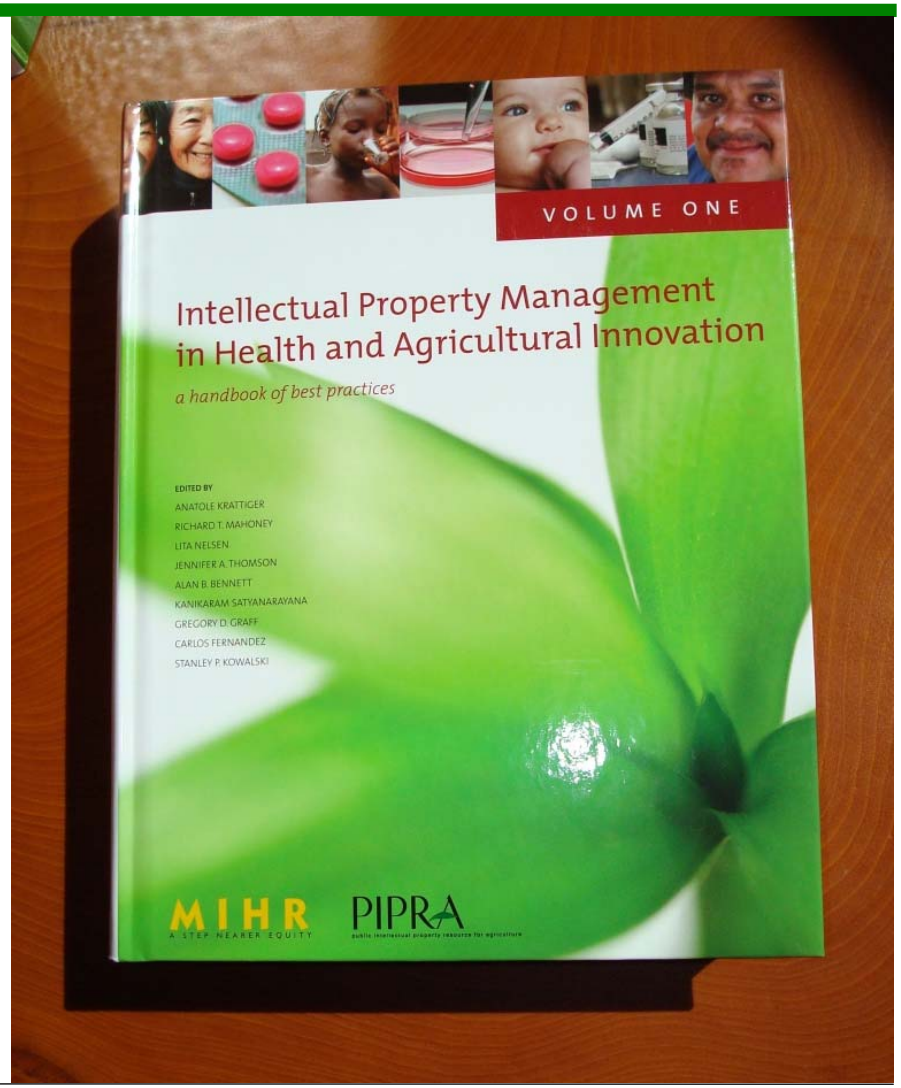
The MIHR-PIPRA IP Handbook

- IP Handbook:
  - 2 volumes
  - 17 sections
  - 153 chapters
- Includes entire sections on…
  - IP treaties
  - IP law
  - Freedom to Operate analysis
  - Alterative structures for IP management



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R&D in the knowledge economy

- Intellectualization of capital base of industry
- "Polyvalence" of emerging technologies
  - breakdown of "basic vs. applied", "product vs. product"
- Stochastic nature yet disproportionate importance of radical innovations
- Plummeting "per unit" research costs
  - Computing power; screening throughput; nucleotide sequencing/synthesis; plant transformation; molecular breeding
- Escalating technological complexity embedded in products
- Escalating regulatory costs
- Breakdown of traditional "linear" model of R&D:
  - "R&D" → "RD"

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R&D in the knowledge economy

- Vertical dis-integration of R&D functions
- Being replaced by robust market-mediated R&D pipelines:
  - IT
  - Pharmaceuticals
  - Spreading to other industries including agriculture

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IPRs and agriculture

- Patents
  - Utility patents
  - Design patents
  - Plant patents
- Trademarks
- Copyrights
- Trade Secrets
- Mask Works*
- Plant Variety Protections*
- Geographical Designations of Origin*

* Industry specific or *sui generis* forms of protection

- Analogous to but weaker than physical property rights
- Old
  - First patent law: Venice 1474
  - First copyright law: Statute of St Anne 1709
  - Written into original US Constitution
- Justifications:
  - Natural Right (Locke)
  - Utilitarian (Mill, Nordhaus, Arrow)

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What does a patent do?

- Gives holder exclusive right to ***use***, ***make***, ***sell***, ***offer for sale***, or ***import***…
  - a ***creation, discovery, improvement upon,*** or ***new use of*** any
    - ***Machine***
    - ***Article of Manufacture***
    - ***Composition of Matter***
    - ***Process*** or ***Method***
  - that is
    - ***Novel***
    - ***Nonobvious***
    - ***Useful***
  - for a term of 20 years.

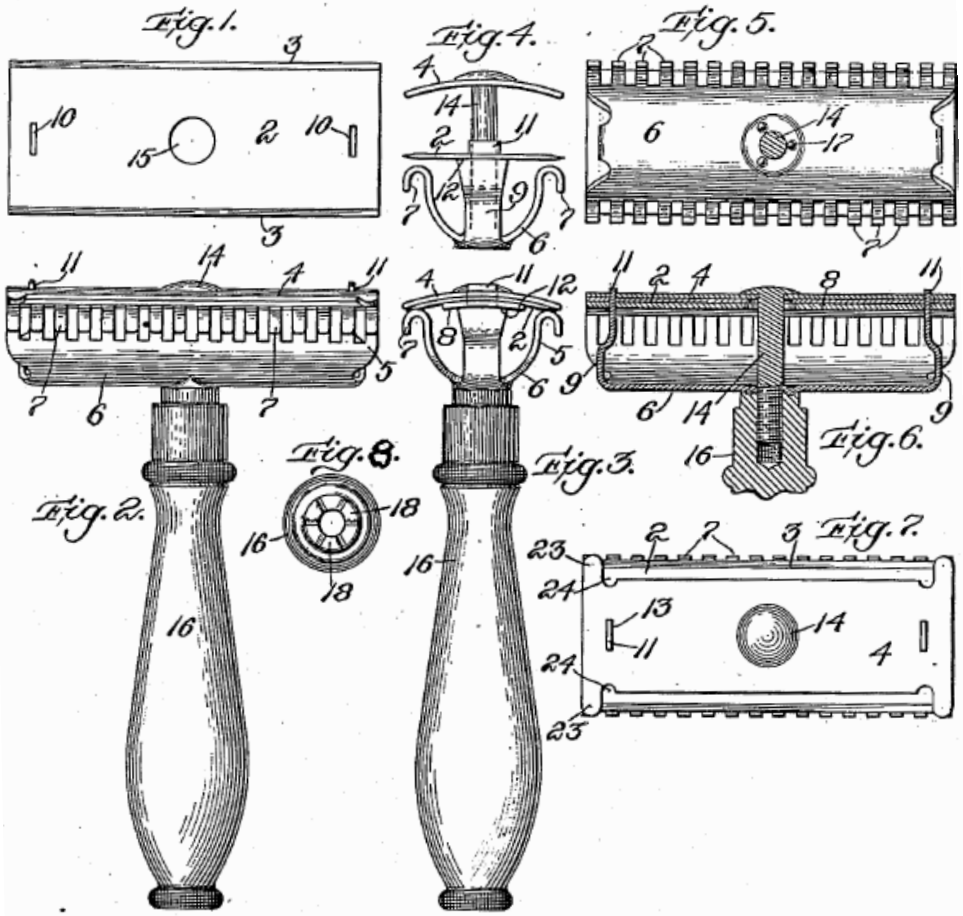
No. 775,134. PATENTED NOV. 15, 1904.

K. C. GILLETTE.

RAZOR.

APPLICATION FILED DEC. 3, 1901.

NO MODEL.



Witnesses:
Ruby M. Banfield.
Margaret A. Dennison.

Inventor:
King C. Gillette,
by
E. G. Chadwick,
Attorney.

(12) **United States Patent**
Page

(10) **Patent No.: US 6,285,999 B1**
(45) **Date of Patent: Sep. 4, 2001**

(54) **METHOD FOR NODE RANKING IN A LINKED DATABASE**

(75) Inventor: **Lawrence Page**, Stanford, CA (US)

(73) Assignee: **The Board of Trustees of the Leland Stanford Junior University**, Stanford, CA (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: **09/004,827**

(22) Filed: **Jan. 9, 1998**

Related U.S. Application Data

(60) Provisional application No. 60/035,205, filed on Jan. 10, 1997.

(51) **Int. Cl.**[7] **G06F 17/30**
(52) **U.S. Cl.** **707/5**; 707/7; 707/501
(58) **Field of Search** 707/100, 5, 7, 707/513, 1–3, 10, 104, 501; 345/440; 382/226, 229, 230, 231

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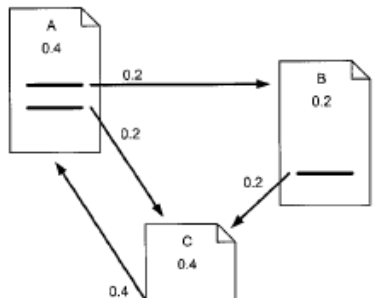
(List continued on next page.)

Primary Examiner—Thomas Black
Assistant Examiner—Uyen Le
(74) *Attorney, Agent, or Firm*—Harrity & Snyder L.L.P.

(57) **ABSTRACT**

A method assigns importance ranks to nodes in a linked database, such as any database of documents containing citations, the world wide web or any other hypermedia database. The rank assigned to a document is calculated from the ranks of documents citing it. In addition, the rank of a document is calculated from a constant representing the probability that a browser through the database will randomly jump to the document. The method is particularly useful in enhancing the performance of search engine results for hypermedia databases, such as the world wide web, whose documents have a large variation in quality.

29 Claims, 3 Drawing Sheets



United States Patent [19]

Cohen et al.

[11] **4,237,224**

[45] **Dec. 2, 1980**

[54] **PROCESS FOR PRODUCING BIOLOGICALLY FUNCTIONAL MOLECULAR CHIMERAS**

[75] Inventors: **Stanley N. Cohen,** Portola Valley; **Herbert W. Boyer,** Mill Valley, both of Calif.

[73] Assignee: **Board of Trustees of the Leland Stanford Jr. University,** Stanford, Calif.

[21] Appl. No.: **1,021**

[22] Filed: **Jan. 4, 1979**

Related U.S. Application Data

[63] Continuation-in-part of Ser. No. 959,288, Nov. 9, 1978, which is a continuation-in-part of Ser. No. 687,430, May 17, 1976, abandoned, which is a continuation-in-part of Ser. No. 520,691, Nov. 4, 1974.

[51] **Int. Cl.**[3] **C12P 21/00**

[52] **U.S. Cl.** ..... **435/68;** 435/172; 435/231; 435/183; 435/317; 435/849; 435/820; 435/91; 435/207; 260/112.5 S; 260/27R; 435/212

[58] **Field of Search** ..... 195/1, 28 N, 28 R, 112, 195/78, 79; 435/68, 172, 231, 183

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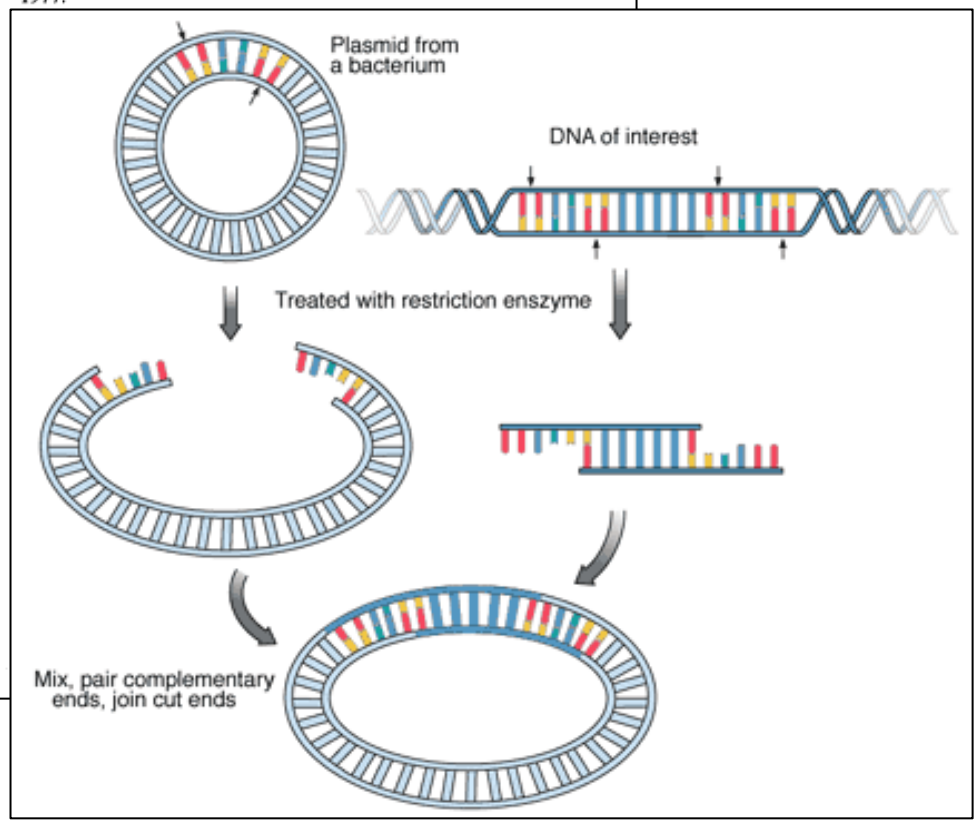

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"Diamond vs. Chakrabarty" July 1980

US Supreme Court (5 to 4) held that living, manmade microorganisms are patentable.

Patents could be issued for "anything under the sun that is made by man."

Chief Justice Warren Burger: "The relevant distinction is not between living and inanimate things," but rather between naturally existing and human-made inventions. Because Chakrabarty's bacterium was created in a laboratory, it was not "nature's handiwork," the court said, but the product of "human ingenuity and research."

A spokesman for Genentech, said the Supreme Court's action had "assured this country's technology future." Genentech's IPO was made in October 1980.

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From microbes to mammals

- Ex parte Hibberd (1985)
  - USPTO Board of Patent Appeals and Interferences extends utility patent protection to plants despite availability of Plant Patents and PVPs
- Ex parte Allen (1987)
  - Board extends patent protection to multicellular animals
- Harvard Mouse patent (1988)
  - USPTO issues patent that claims a mammal
- JEM Ag Supply v. Pioneer Hi-Bred (2001)
  - US Supreme Court confirms patents over plants

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Bayh-Dole Act (1980)

- Universities may elect title to inventions created under U.S. federal funding
- Patents must be filed by the University
- University must have written agreements with faculty and staff requiring disclosure and assignment of inventions
- University must share a portion of revenue with inventors
- Excess revenue must support research and education
- Government retains non-exclusive license to the invention
- Government retains march-in rights
- Preference in licensing to small businesses
- Requirement for substantial U.S. manufacture

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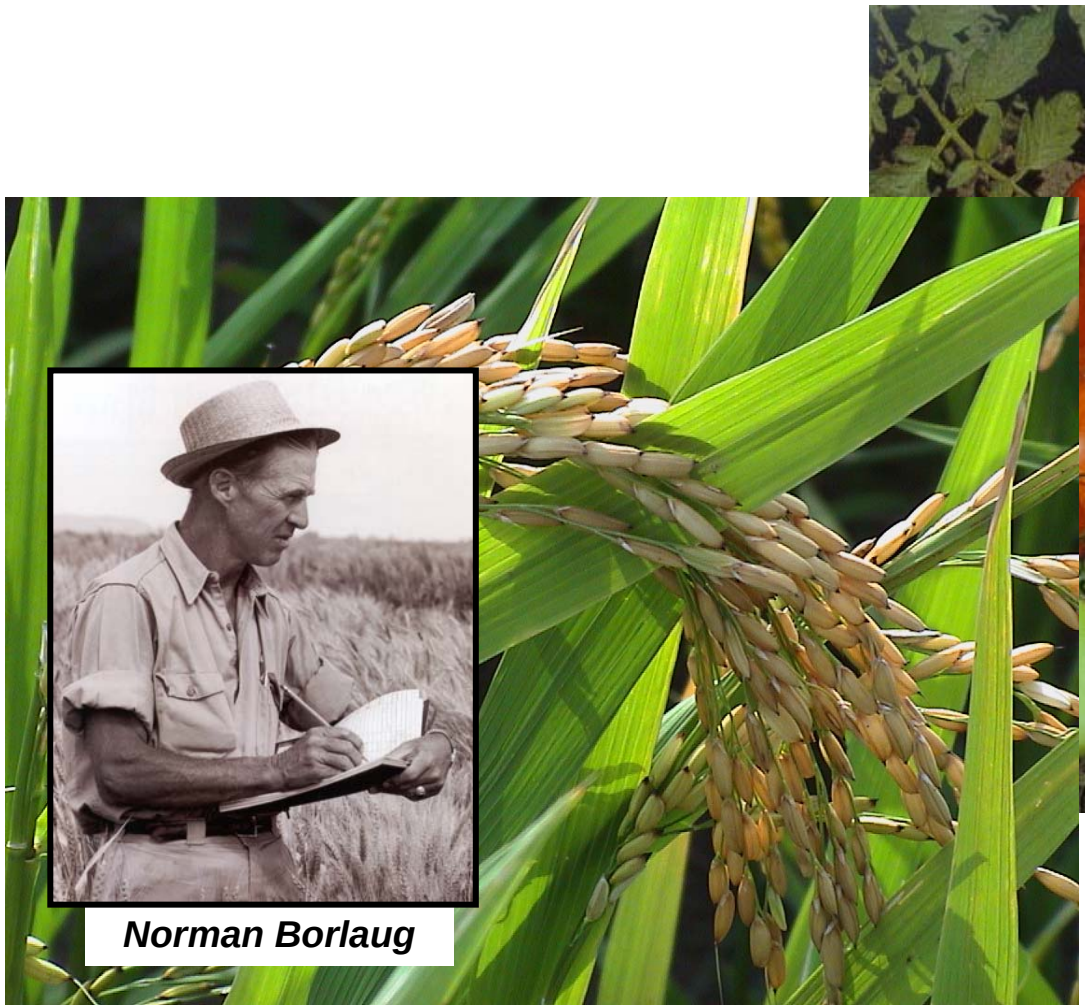
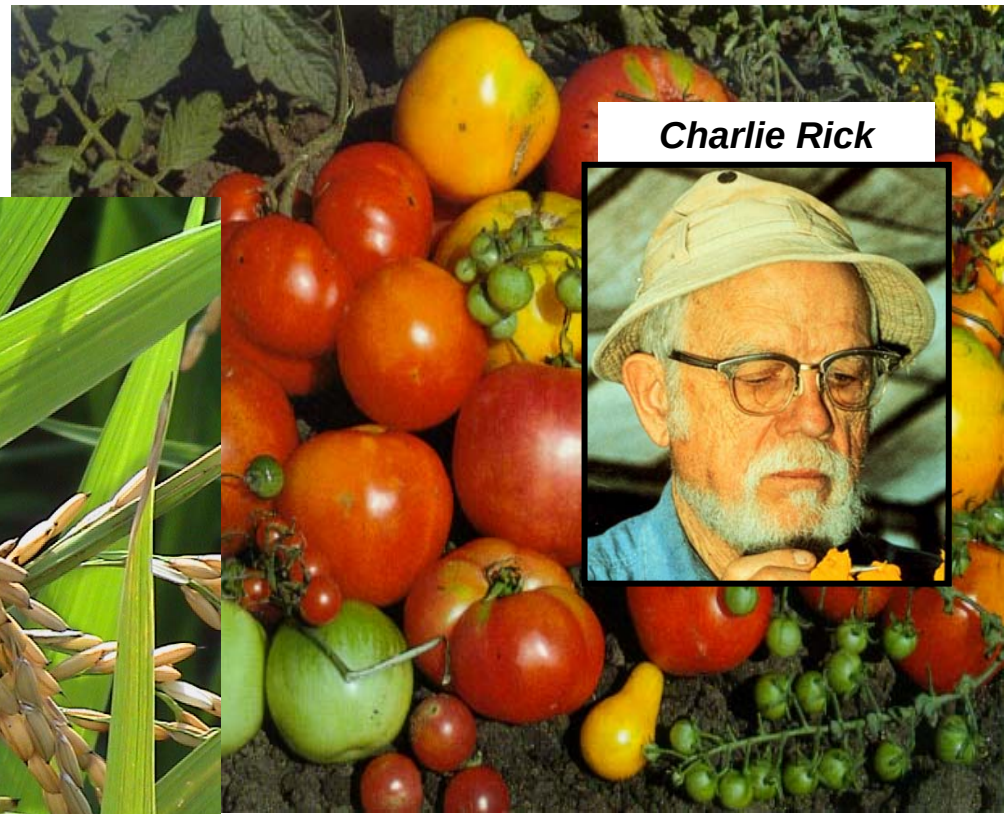
Agricultural R&D – historically a public good





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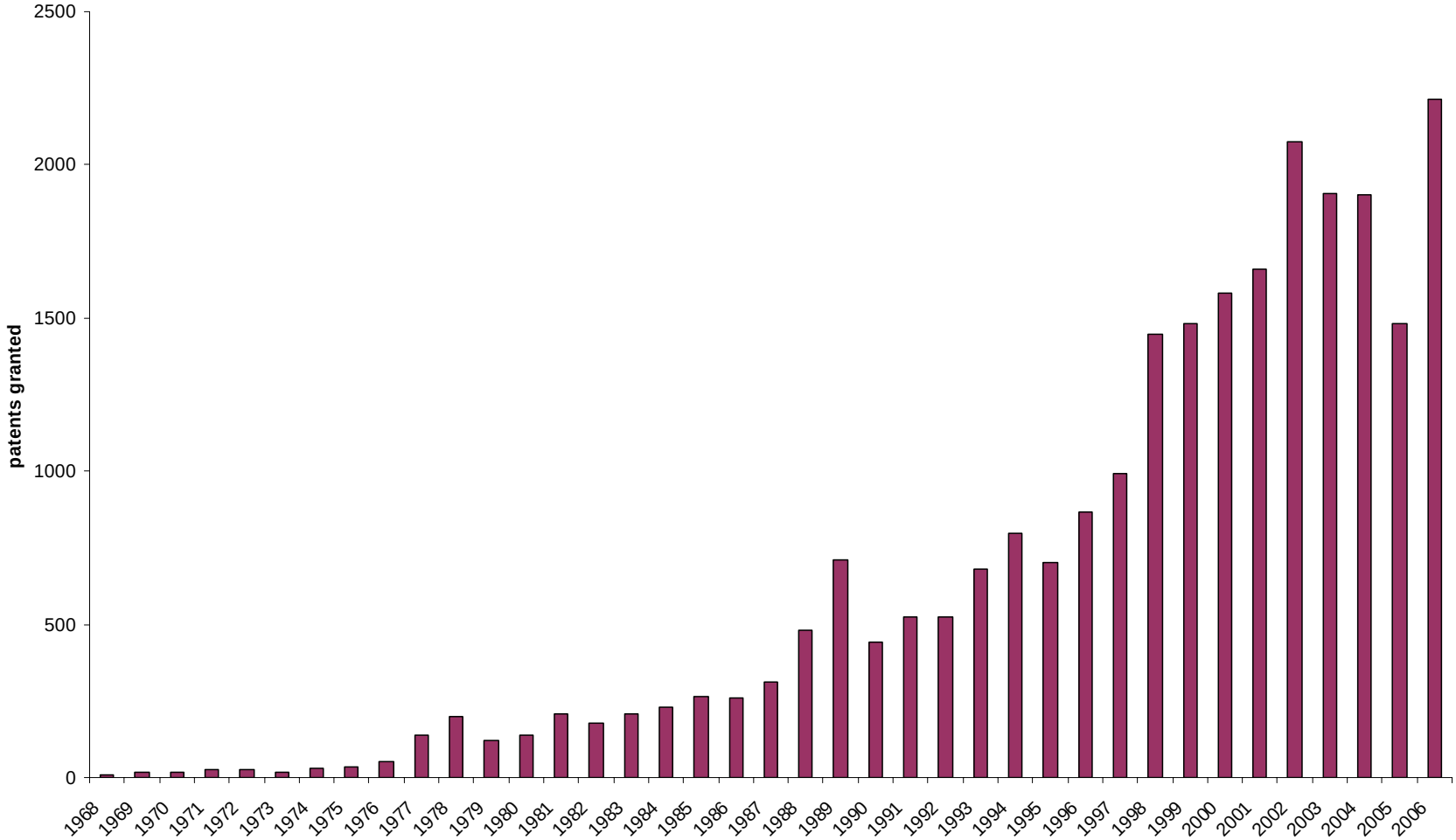
US patents granted in plant genetics and biotechnology



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Freedom to Operate

- ***An acceptably low risk of others' IP being enforced against you***
  - It is a risk calculation
  - No absolute "freedom"
- Risk increases with the density of IP ownership around a technology
- Risk increases as technology advances to market
  - Early stage technologies not likely targets
  - Need for FTO analysis increases along development cycle
- Universities/governments not assured FTO
  - No formal "research exemption" in US (in Canada?)
  - Madey v. Duke University narrowed *implicit* research exemption
  - Determines opportunities for technology transfer

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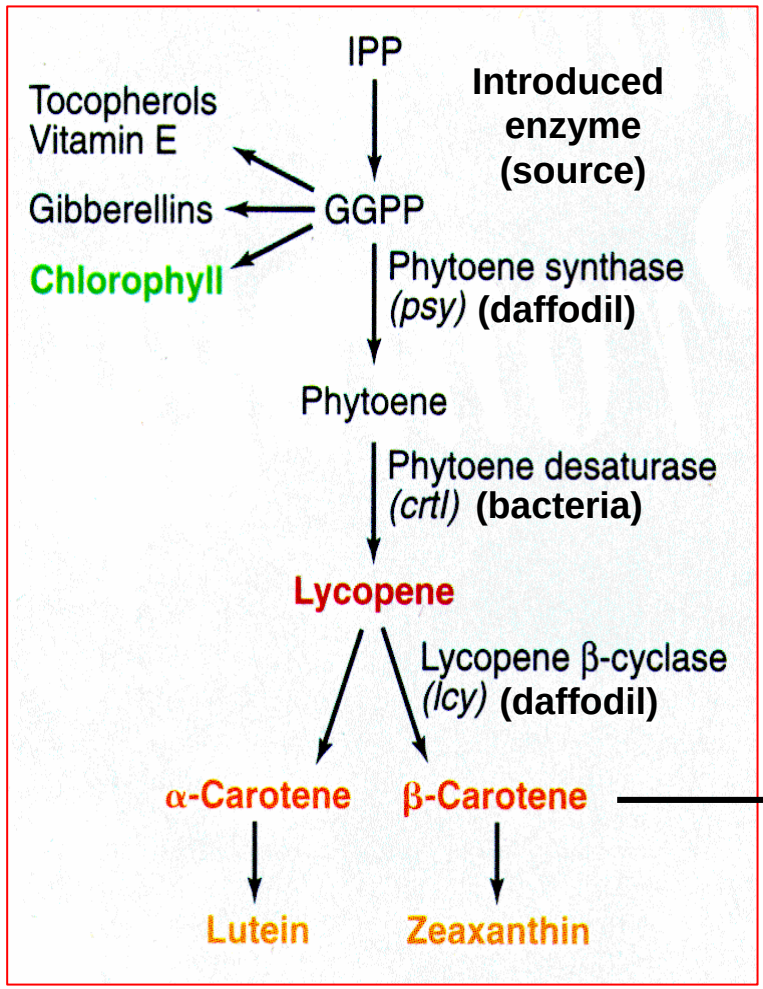
FTO for Golden Rice

70 proprietary technologies (40 US patents)

- **Uncertainty**
- **High transaction costs**



"Golden" rice

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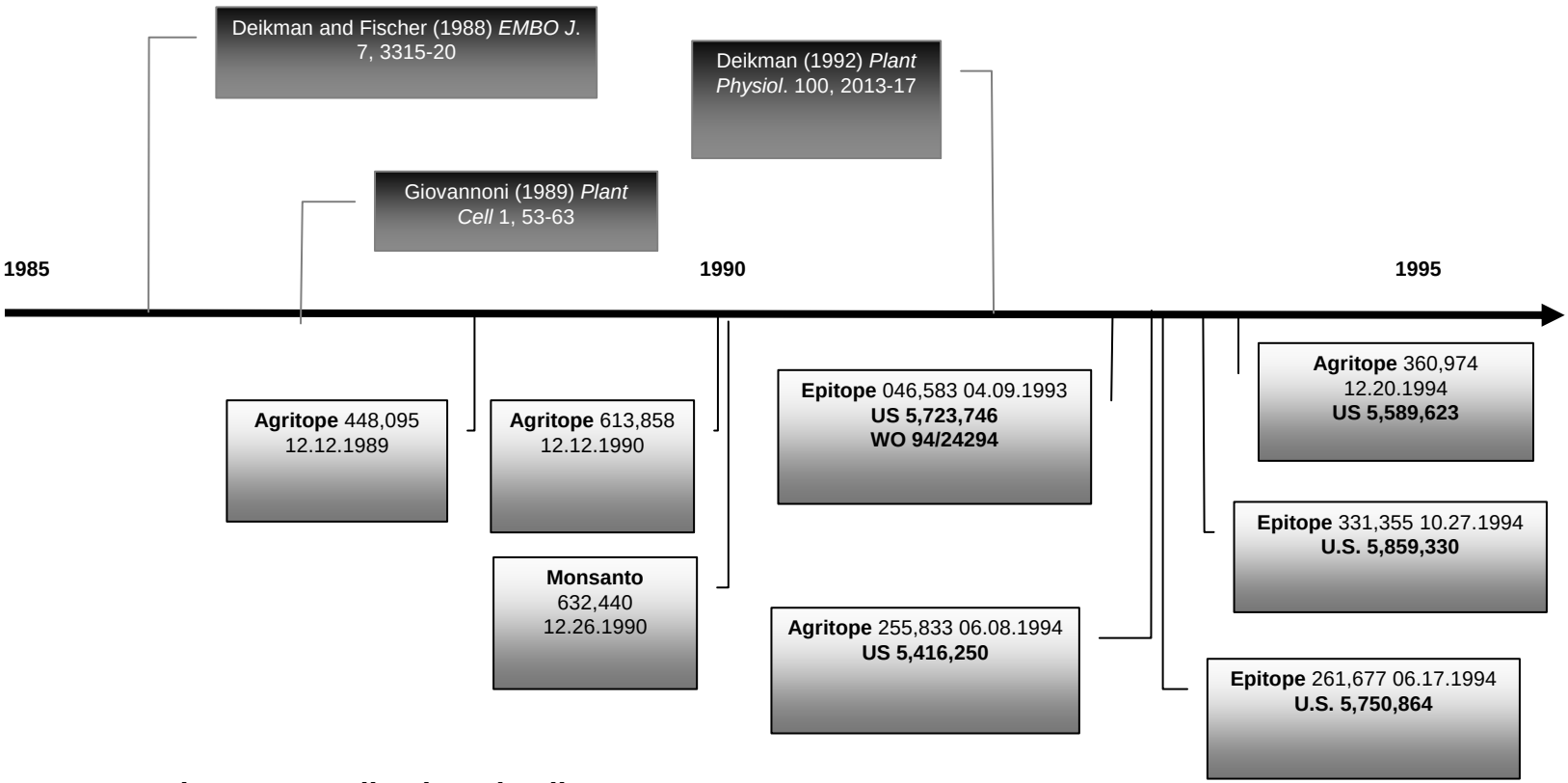
FTO for Fruit E8 promoter

Literature Timeline



Patent and Patent Application Timeline

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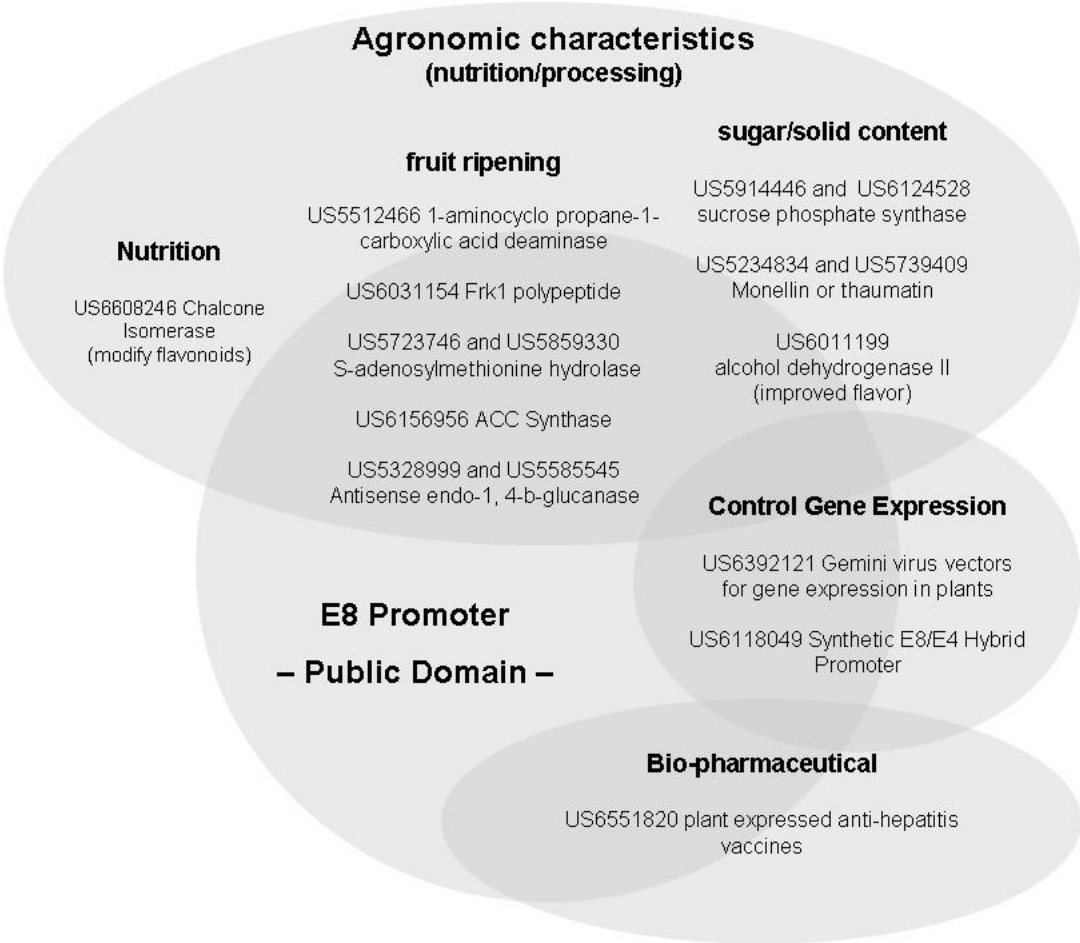
FTO for Fruit E8 promoter



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The market for IPRs

- IPRs
  - Provide freedom to operate (“defensive”)
  - Provide exclusivity (“offensive”)
- Can sell or write a contract over either aspect of the right:
  - Nonexclusive right to use (FTO)
  - Exclusive right to use

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The market for IPRs

- Full spectrum of transaction types:

Full acquisition and integration of company with IPR	**Partial acquisition of company with IPR**	**Strategic research partnership or joint venture**	**Ongoing R&D contract**	**Purchase or exclusive license of IPR**	**Non-exclusive license of IPR; purchase of technology input**

Most internalized ⟷ **Most externalized or "arms-length"**

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The market for IPRs

- Subject to market failures:
  - Poorly defined property rights
  - Lack of competition in supply (and demand)
  - Incomplete/asymmetric information
  - Costly transactions
- Results in agricultural biotechnology:
  - Horizontal consolidation of IPR portfolios by major companies
  - Economic infeasibility of developing minor market applications

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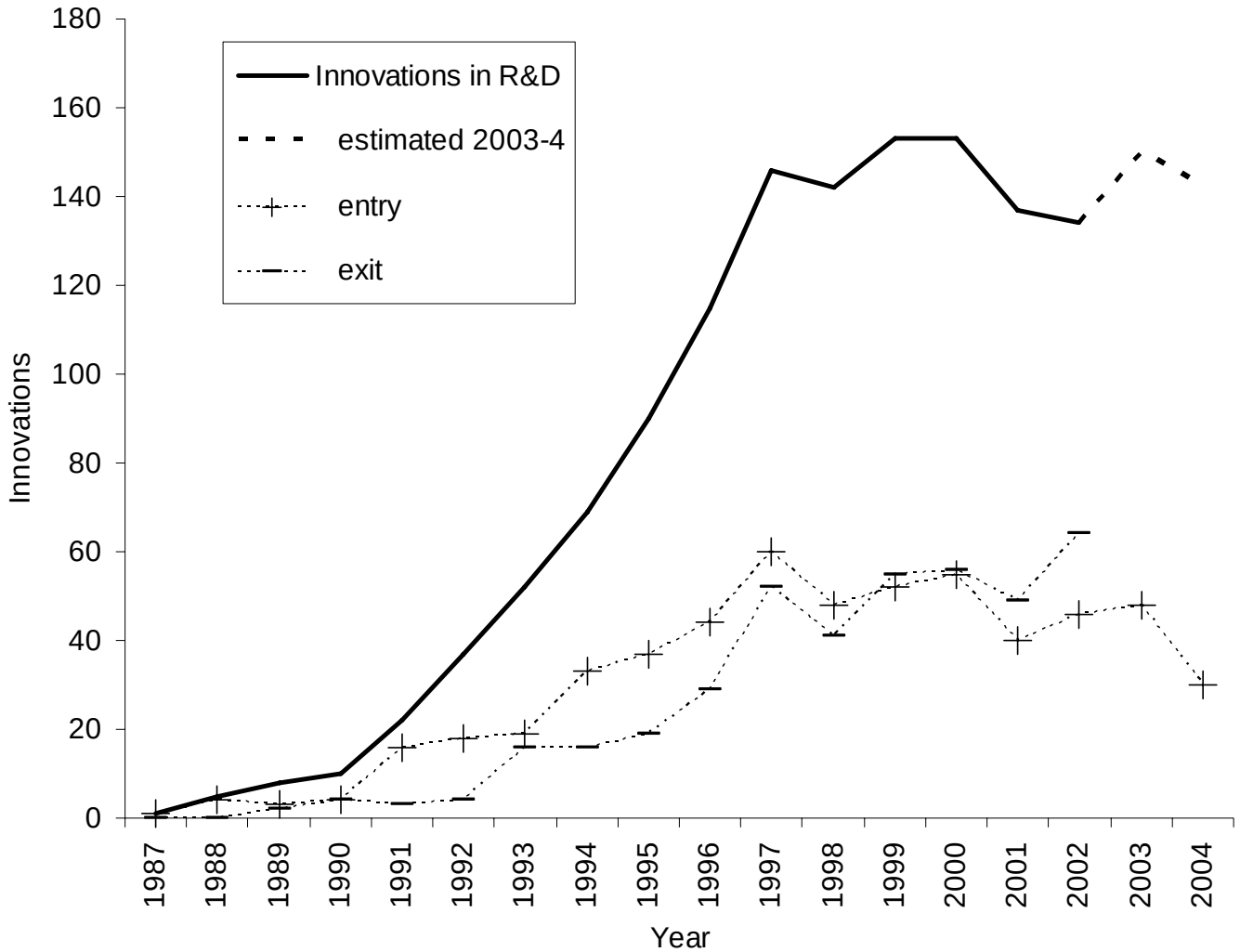
Impacts in agbiotech R&D



Number of product quality output trait innovations being actively pursued in the global agbiotech R&D pipeline.

Source: Graff, Zilberman, & Bennett, forthcoming

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Alternative structures

- Solve market failures by allowing open access within the public domain?
  - Approach taken by
    - Human Genome Project
    - SNP Consortium/HapMap Project
  - Introduces other well-know failure:
    - Underinvestment in private R&D

- Several alternative structures seek best of both worlds by developing a “protected commons” that treats IP protected technologies as quasi-public goods.
  - Collective actions among private agents to preserve common IP resources for mutually beneficial activity.
  - Unilateral actions by public agents that own and use IPRs for public good

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Alternative structure: PDPs

- Product development partnership model emerged in late 1990s to advance neglected disease R&D: TB Fund, IAVI, MVI, DNDi, PATH, iOWH
- Non-profit organizations
  - Operate like biotech or specialty pharma companies
  - Own or in-license or IP: about 1/3 from academia, 2/3 from companies
  - Manage R&D “virtually” coordinating contributions from both public and private R&D partners
  - Use IP to out-license, share rights, or establish distributor agreement with private partner(s) for selling/distributing drug/vaccine on terms beneficial to public health

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Alternative structure: Open Source

- Two models developed in software differ in stringency of "grant back" requirements for improvements
  - Richard Stallman's Free Software and the GNU General Public License
    - Requires all users/developers to assign copyright to the Free Software Foundation controlled by Stallman
    - Has forced developers who incorporated free software into proprietary products to open up their source code
  - Linus Torvald's LINUX and Open Source Software licenses
    - Allows users/developers to retain rights selectively, not grant them back to open source community
    - More business friendly

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Alternative structure: Open Source

- Model is being adapted to agriculture
  - Richard Jefferson's "TransBacter" plant transformation method under the BiOS license
    - Licensees may use the technology, but must grant non-exclusive license for any improvements back to the entire community of BiOS licensees
    - Fairly strong grant back requirements, not clear if more like Free Software movement or Open Source software model
    - Based on patents, not copyright (more costly to register and enforce)

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Alternative structure: patent pools

- A common license to a set of technologies owned by multiple parties
- Often form around industry standards
- An old concept, recently revived
  - Manufacturers Aircraft Association (MAA) formed in 1917
  - Automobile industry patent pool in the 1920s and 30s
  - MPEG patent pool formed in late 1990s
- Untried in the life sciences
- Being attempted by group of universities for agricultural biotechnology: PIPRA

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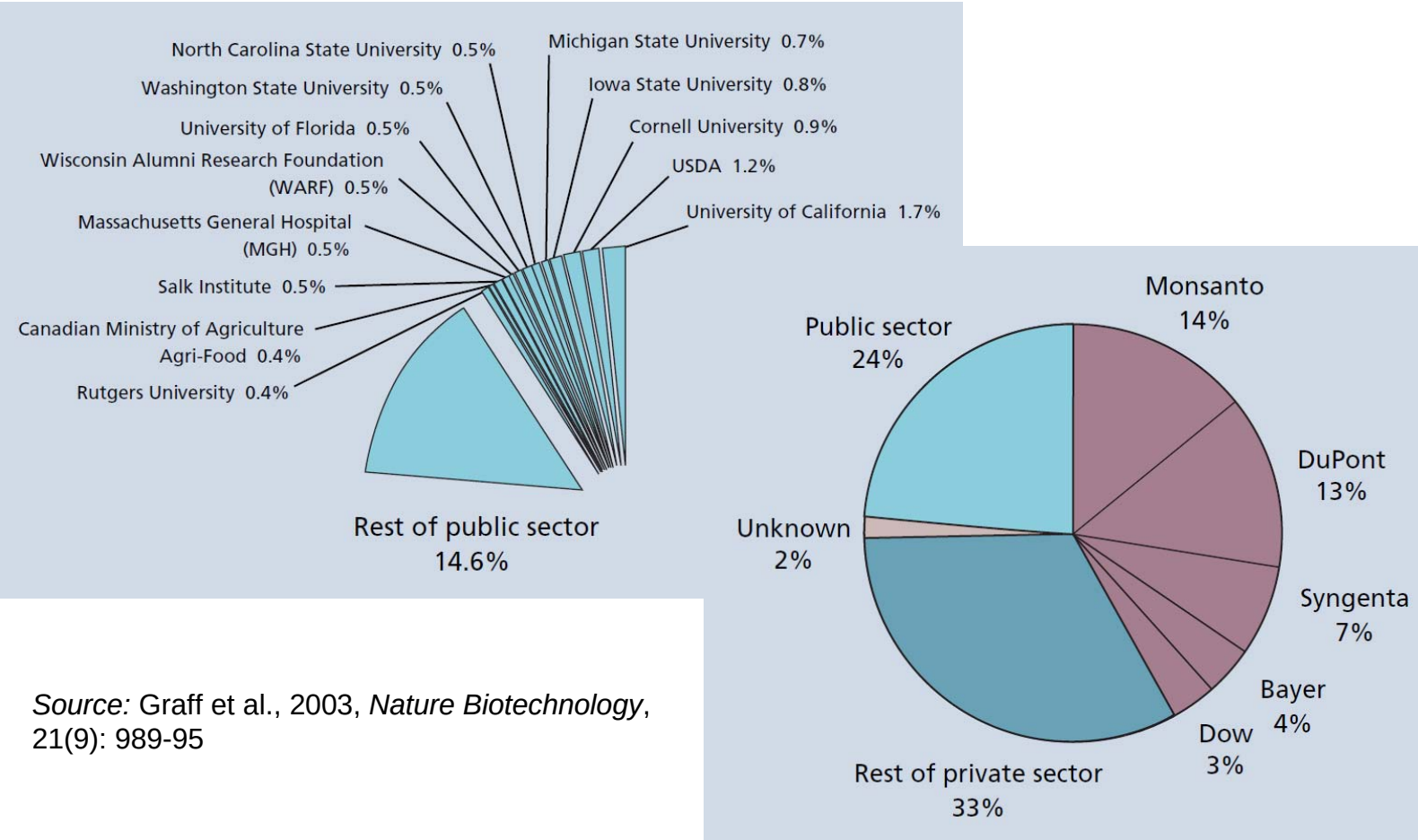
Assignment of US patents granted in agbiotech 1982-2001



Source: Graff et al., 2003, *Nature Biotechnology*, 21(9): 989-95

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POLICY FORUM

INTELLECTUAL PROPERTY RIGHTS

Public Sector Collaboration for Agricultural IP Management

Richard C. Atkinson, Roger N. Beachy, Gordon Conway, France A. Cordova, Marye Anne Fox, Karen A. Holbrook, Daniel F. Klessig, Richard L. McCormick, Peter M. McPherson, Hunter R. Rawlings III, Rip Rapson, Larry N. Vanderhoef, John D. Wiley, Charles E. Young

(3). However, these practices are not universally applied across institutions, with the net 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

"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."

"What is the balance between the positive effects of IP rights on your institutional mission and the limitations these rights place on your research and your ability to apply your discoveries for the greatest public benefit? PIPRA seeks wide participation to mobilize the full scientific capacity as well as the underlying IP for public-sector agricultural research."

model is changing rapidly because of increased intellectual property (IP) protec-

Annual grants of U.S. utility patents in the area of plant biotechnologies.

multiple public- and private-sector owners, this fragmenta-

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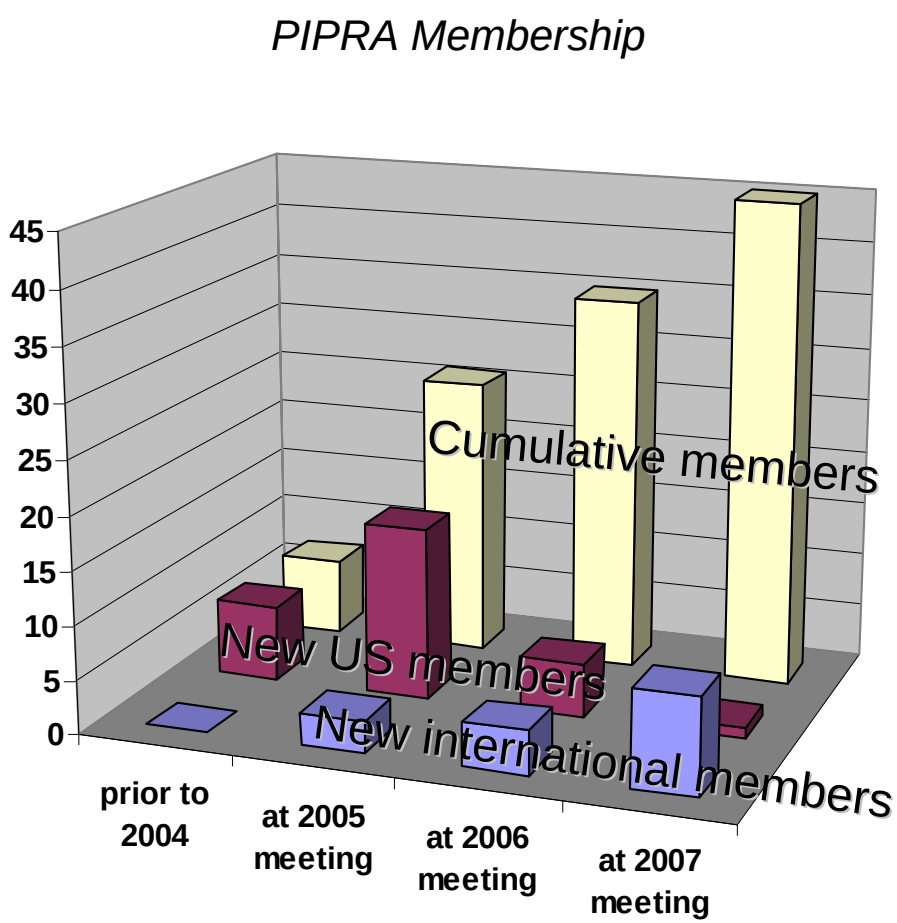
PIPRA membership



1. Agriculture and Agri-Food Canada
2. Arizona Technology Enterprises/Arizona State University
3. AVRDC-The World Vegetable Center
4. Barwale Foundation
5. Birla Institute of Technology
6. Boyce Thompson Institute
7. China Agricultural University
8. CIMMYT-International Maize and Wheat Improvement Center
9. CIP-International Potato Center
10. Cornell University
11. Donald Danforth Plant Science Center
12. Fundacion Chile
13. Hanoi Agricultural University
14. Institut de Recerca I Tecnologia Agroalimentaries-IRTA
15. Institute of Agricultural Genetics
16. Institute of Agricultural Research –INIA
17. Iowa State University
18. IRRI-International Rice Research Institute
19. Kansas State University
20. Michigan State University
21. North Carolina State University
22. Ohio State University
23. Oregon State University
24. Parco Tehnologico Padano
25. Purdue University
26. Rutgers
27. Salk Institute
28. Samuel Roberts Noble Foundation
29. St Augustine University of Tanzania
30. University of Arizona
31. University of Arkansas
32. University of California, Berkeley
33. University of California, Davis
34. University of California, Riverside
35. University of Florida
36. University of Georgia
37. University of Idaho
38. University of Kentucky Research Foundation
39. University of Minnesota
40. University of Missouri-Columbia
41. University of Saskatchewan
42. University of Tennessee
43. Virginia Polytechnic Institute
44. Washington State University
45. Wisconsin Alumni Research Foundation

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PIPRA patent pool project

PIPRA Vector Workshop

Danforth Center, St Louis

October 2004

- **Identify technical, legal, and regulatory design parameters for vector**
- **Characterize the FTO landscape around vector components**
- **Identify PIPRA-owned or public domain technologies that may work around FTO 'road blocks'**

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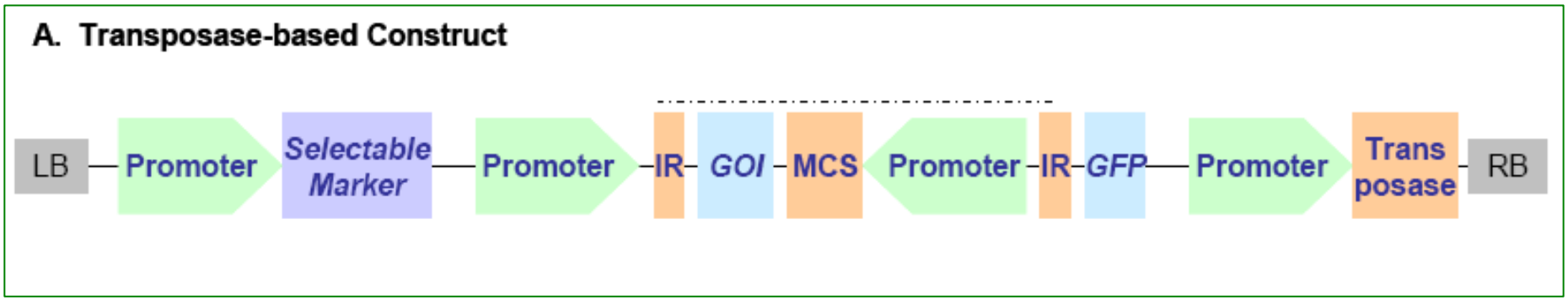
pPIPRA Plant Transformation Vector, version 1.0



Transposon segregation:

1. **University of California**

Promoters:

1. **University of California**
2. **University of Georgia**
3. **Cornell University**
4. **AgriFood Canada**
5. **Public domain**

Selectable markers:

1. **University of Kentucky**
2. **University of Tennessee**

Delivery:

1. ***Agrobacterium* (public domain)**
2. ***Rhizobium* (CAMBIA/BiOS or public domain)**

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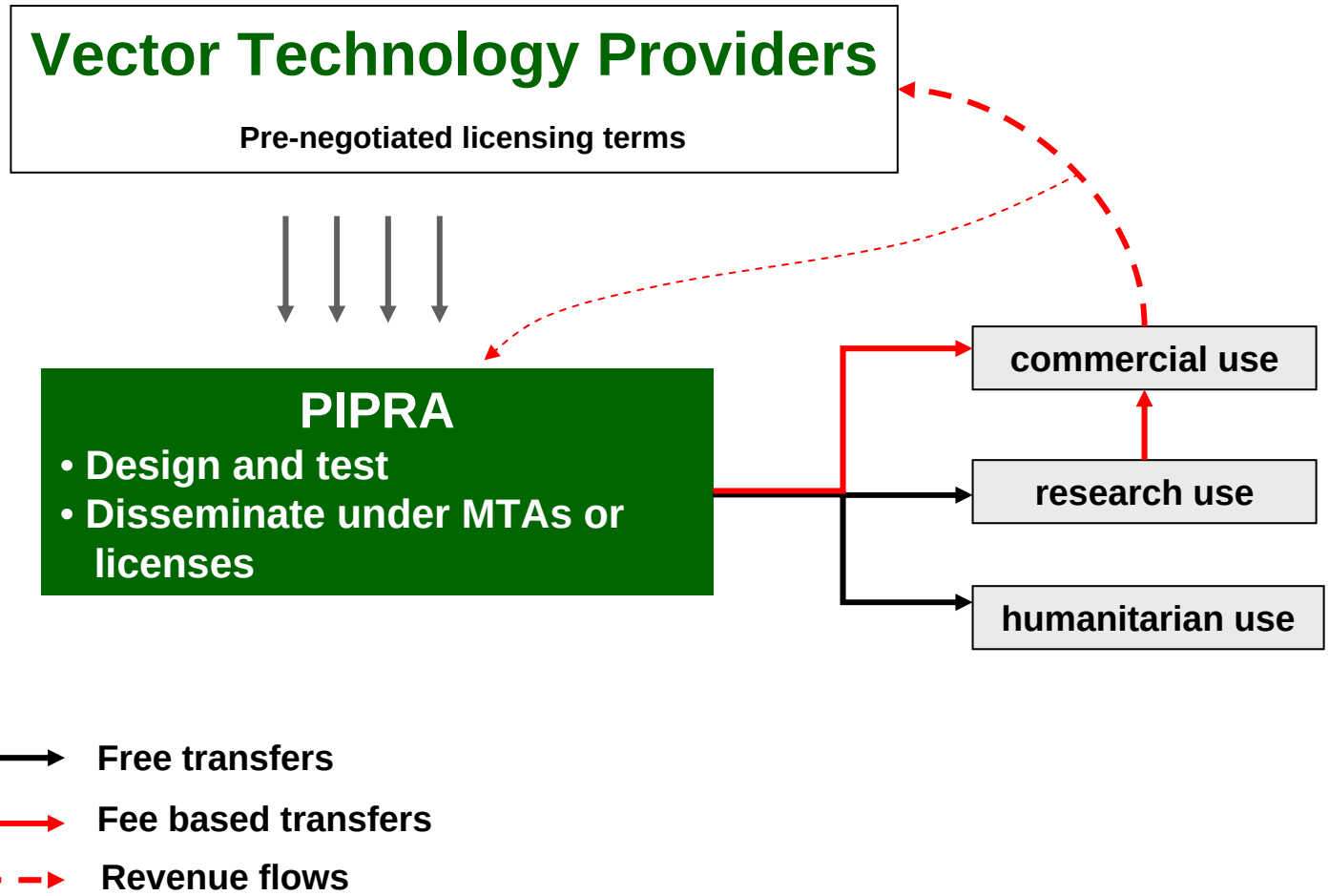
Vector pool licensing model



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PIPRA patent pool

- Comments by a small seed company, prospective licensee of the PIPRA vector patent pool:
  - "Lowers financial barriers to entry"
  - "Promotes entrepreneurialism among smaller companies"
  - "Provides otherwise non-existent opportunities"
  - "Absence would result in entrepreneurial disincentive and a virtual monopoly by the biotechnology 'Titans' "
  - "Can play a critical role 'leveling the playing field' "

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PIPRA patent pool

- Comments by an agricultural research PDP in Africa, a prospective humanitarian licensee:
  - "Clarifies IP rights for Sub-Saharan Africa, even if there is no IP enforced in target countries"
  - "Humanitarian basis allows us access to a license royalty-free, with no fee and no royalty payments needed"
  - "Clarifies ownership of improvements"
  - "Allows Africans to export products for food and feed purposes outside Africa."

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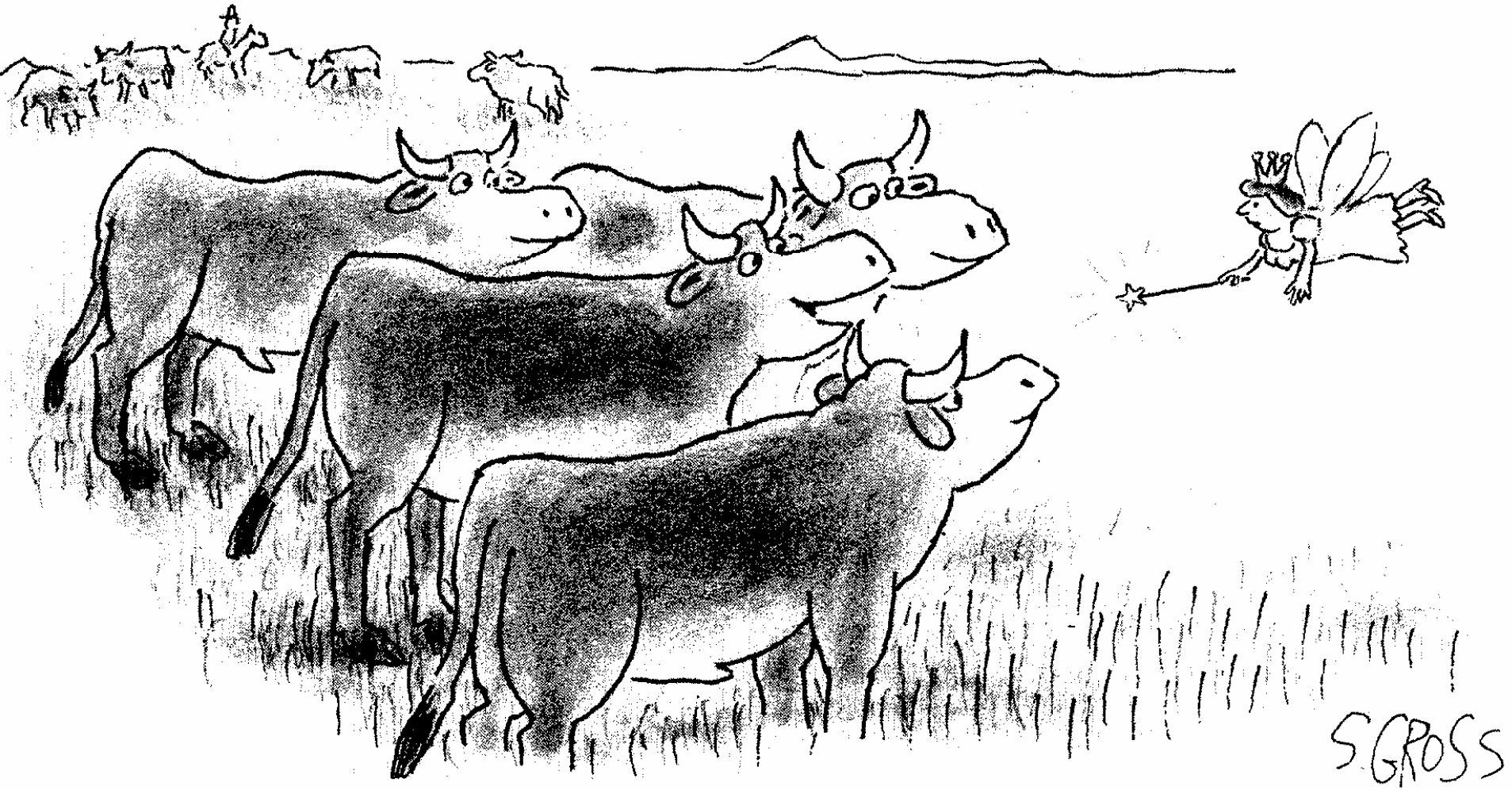
PIPRA offices in Department of Plant Sciences at UC Davis



"We would like to be genetically modified to taste like Brussels sprouts."