



# Academic Freedom and Commercial Academic-Industry Relationships

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GREGORY

*"I'd like your honest, unbiased and possibly career-ending opinion on something."*





## The Take-Home Message

- Commercial academic-industry relationships (AIRs) frequently result in restrictions on academic research.
- The academic community believes that many of those restrictions are especially egregious, and criticizes them on the grounds that they constitute restrictions on academic freedom.
- Establishing the soundness of those criticisms is challenging, on both empirical and conceptual grounds.
- But in spite of those challenges, many of the examples are truly problematic, and academic freedom still plays an important conceptual role in explaining why those restrictions are unacceptable.



# Outline

- General Background on AIRs and Some Problematic Examples
  - Academic use of materials for which they need a license from industry
  - Industry funding of research
- Two Accounts of the Value of Academic Freedom
  - Consequentialist Account
  - Rights-based Account
- The Challenge
  - Paucity of data relevant for a consequentialist assessment
  - The right to academic freedom is easily waived and limited in scope
- Getting Beyond the Challenge



# Commercial Academic-Industry Relations

- AIRs = commercial relationships between for-profit companies and academic faculty, academic staff, or academic institutions



## Kinds of AIRs

- Blumenthal 1992
  - Academic consulting for industry
  - Academic involvement in start-up companies
  - Industry support of graduate students or postdocs
  - Industry funding of academic research
  - Sale or licensing of patents by universities to industries
  
- Academic use of materials for which they need a license from industry



## Kinds of AIRs

- My focus:
  - Academic use of materials for which they need a license from industry
  - Industry funding of academic research

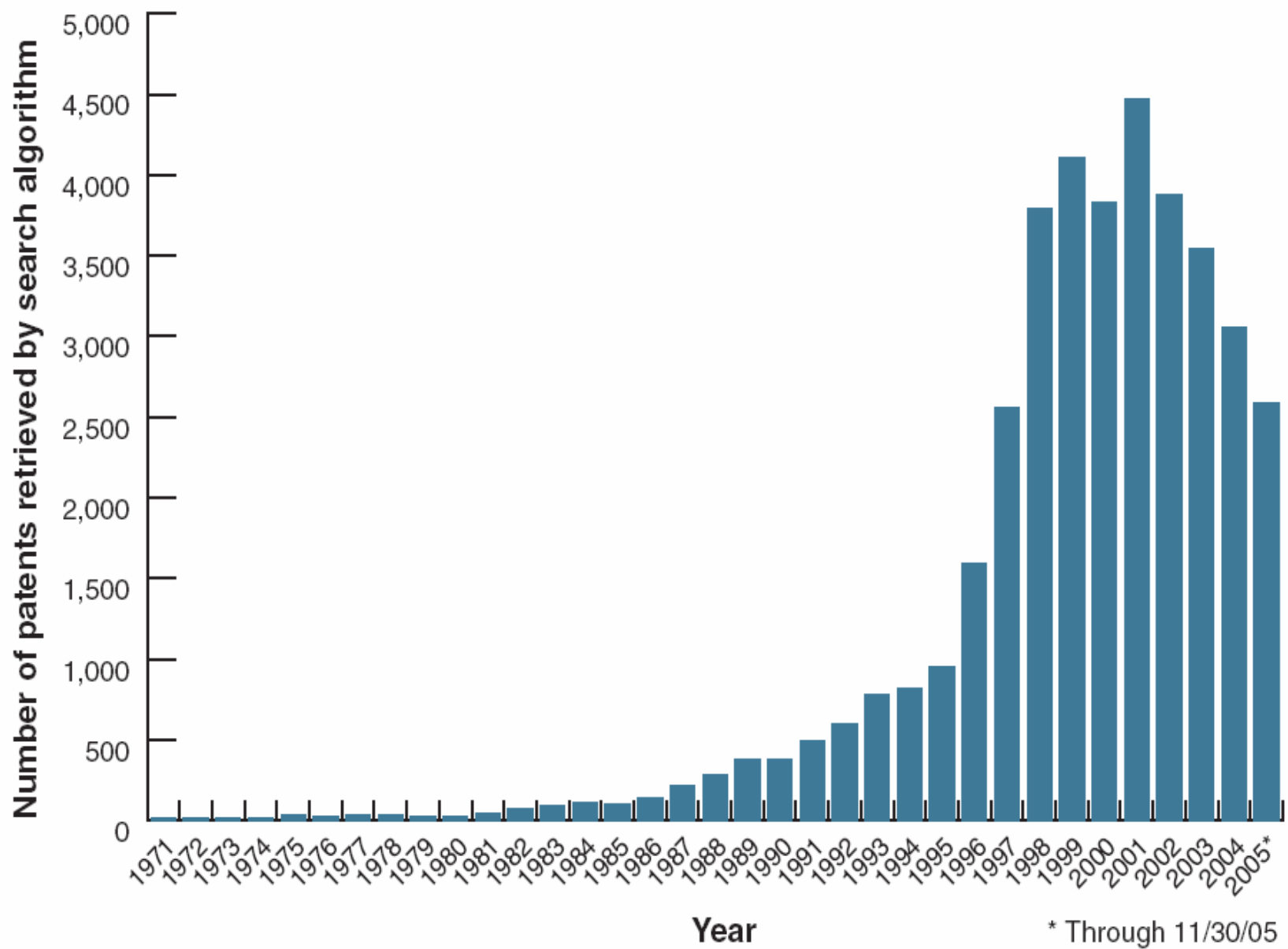




# Some Background on "DNA" Patents

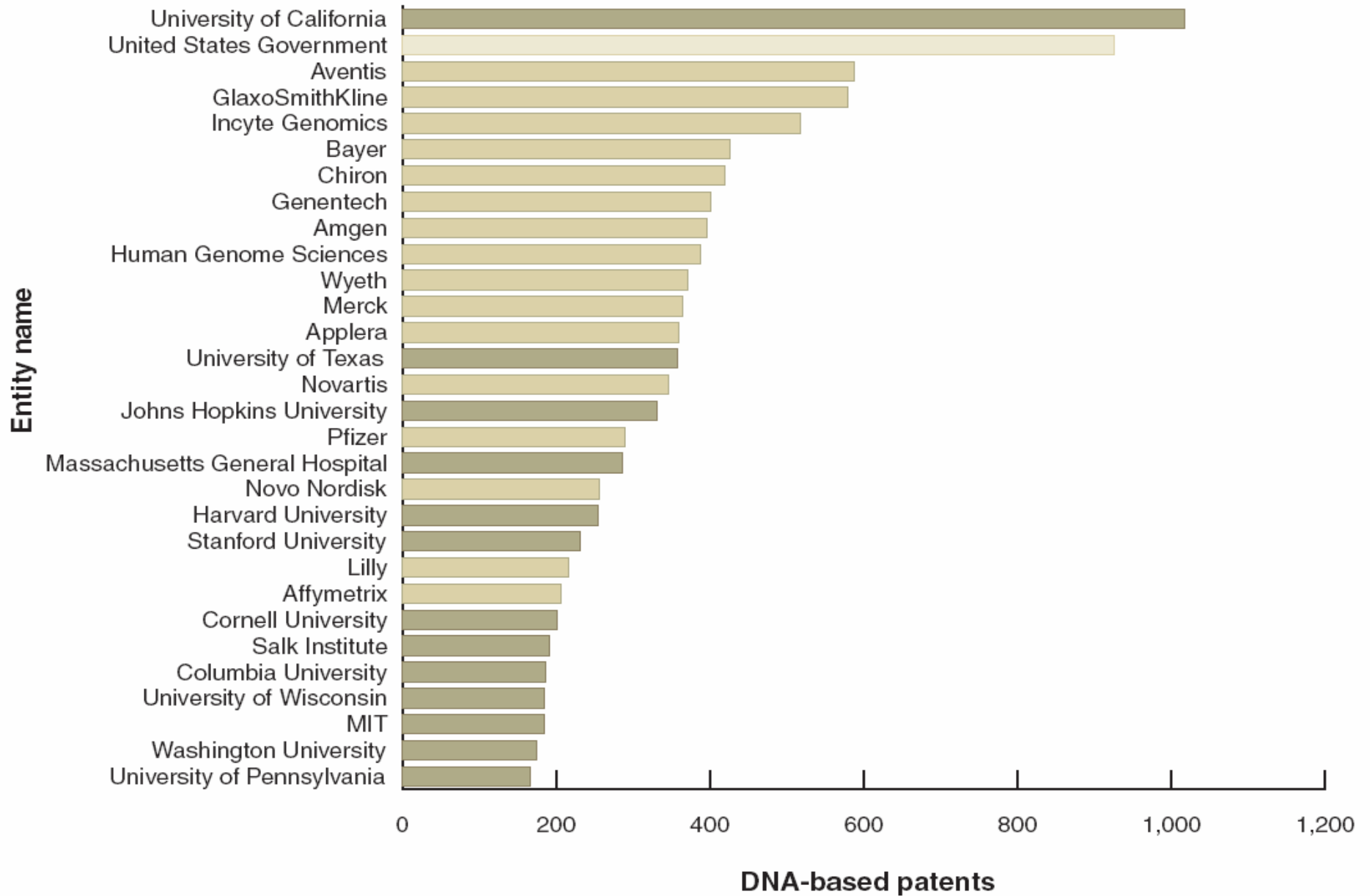
**Table 1** Examples of DNA patents captured by the search algorithm

US patent number	Title
4613566	Hybridization assay and kit
4643969	Novel cloning vehicles for polypeptide expression in microbial hosts
4948733	Zoogloea transformation using exopolysaccharide noncapsule producing strains
4970154	Method for inserting foreign genes into cells using pulsed radiofrequency
5097025	Plant promoters
5169939	Chimeric antibodies
5215904	Method for producing a recombinant mammal <i>in vivo</i>
5266459	Gaucher's disease: detection of a new mutation in intron 2 of the glucocerebrosidase gene
5348878	Class I major histocompatibility complex (MHC)-restricted T-T hybridomas, and a CD8-transfected BW5147, fusion partner
5521071	Soluble LDL receptor and gene
5558998	DNA fragment sizing and sorting by laser-induced fluorescence
5569824	Transgenic mice containing a disrupted p53 gene
5571671	Method for detecting Alzheimer disease
5624823	DNA encoding porcine [sic] interleukin-10
5681934	47-kilodalton antigen of <i>Treponema pallidum</i>
5750347	<i>In situ</i> polymerase chain reaction
5785965	Vascular endothelial growth factor gene transfer into endothelial cells for vascular prosthesis
5837244	Oncoprotein protein kinase
5874304	Humanized green fluorescent protein genes and methods
5917025	Human telomerase
5981842	Production of water stress or salt stress tolerant transgenic cereal plants



**Figure 2** Number of US DNA patents issued 1971–2005.

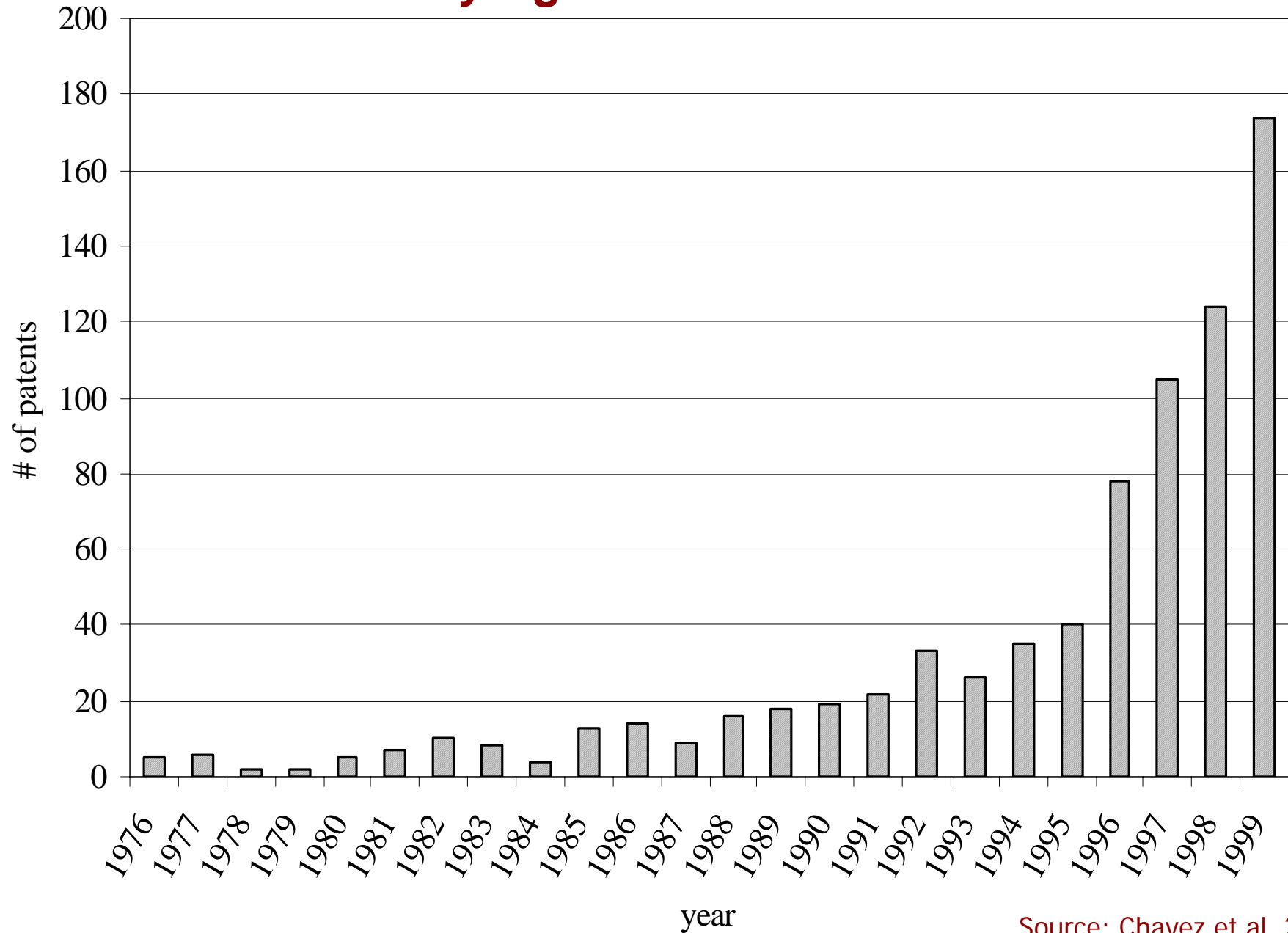
Source: Pressman et al., 2006



**Figure 3** The top 30 entities holding the largest number of DNA-based US patents.

Source: Pressman et al., 2006

# U.S. University Ag-Biotech Patent Production



Source: Chavez et al. 2005



# Patent Example 1: Ingo Potrykus and "Golden Rice"

- Ingo Potrykus, at the Swiss Federal Institute of Technology in Zurich
- "Golden Rice"





# Patent Example 1: Ingo Potrykus and "Golden Rice"

Table 1: Product Clearance Profile: Possible Required Licenses and/or Agreements for GoldenRice™

Name of Institution	Possible Applicable Patents
1. AMOCO	US5545816, EP0471056, US5530189, WO9113078, US5530188, US5656472
2. Bio-Rad Inc.	US5186800
3. Biotechnica	WO8603516
4. Calgene	WO9907867, WO9806862
5. Centra National de la R.S.K.	WO9636717
6. Cetus	WO8504899, US4965188, EP0258017
7. Columbia Univ. of New York	US4399216, US4634665, WO8303259
8. DuPont	WO9955889, WO9955888, WO9955887
9. Eli Lilly	US5668298
10. Hoffman-La-Roche	US4683202, EP0509612, EP0502588, US4889818
11. ICI, Ltd.	WO9109128,
12. Japan Tobacco	EP0927765, US5591616, EP0604662, EP0672752, US5731179, EP0687730, WO9516031
13. Kirin Brewery	JP3058786, US5429939, US5589581, EP0393690, US5350688
14. Life Technologies	
15. Max Planck Gesell.	EP0265556, EP0270822, EP0257472
16. Monsanto	US5352605, US5858742, WO8402913
17. National Foods RI	JP63091085
18. N.R.C. Canada	WO9419930
19. Novartis AG	
20. Nederlandse O.V.T.	EP0765397, WO9535389
21. Phytogen	US4536475
22. Plant Genetic Systems	US5717084, US5778925, WO8603776, WO9209696
23. Promega	US4766072
23. Rhone-Poulenc Agro	USRE36449, WO9967357
24. Rutgers University	
25. Stanford University	US4237224
26. Stratagene	US5128256, US5188957, US5286636, EP0286200, WO880508
27. University of Maryland	WO9963055
28. University of California	US4407956, WO9916890
29. Washington State University	
30. Yissum R.D.C.	US5792903, EP0820221, WO9628014
31. Zeneca Corp.	US5750865, EP0699765A1

Note that these are the names of the owners or assignees of the rights under the relevant patents. Because of possible subsequent licensing or assignment, these are not necessarily the current entities to approach for licenses.

Source: Kryder et al. 2000



## Patent Example 1: Ingo Potrykus and "Golden Rice"

- "It seemed to me unacceptable, even immoral, that an achievement based on research in a public institution and with exclusively public funding, and designed for a humanitarian purpose, was in the hands of those who had patented enabling technology early enough.... At that time I was much tempted to join those who radically fight patenting." (Potrykus, "The Golden Rice Tale")



# Patent Example 1: Ingo Potrykus and "Golden Rice"

- Illustrates the "tragedy of the anticommons"

"multiple owners each have a right to exclude others from a scarce resource and no one has an effective privilege of use." (Heller and Eisenberg 1998)

## Can Patents Deter Innovation? The Anticommons in Biomedical Research

Michael A. Heller and Rebecca S. Eisenberg

The "tragedy of the commons" metaphor helps explain why people overuse shared resources. However, the recent proliferation of intellectual property rights in biomedical research suggests a different tragedy, an "anticommons" in which people underuse scarce resources because too many owners can block each other. Privatization of biomedical research must be more carefully deployed to sustain both upstream research and downstream product development. Otherwise, more intellectual property rights may lead paradoxically to fewer useful products for improving human health.

could set up shop without first collecting rights from each of the other owners.

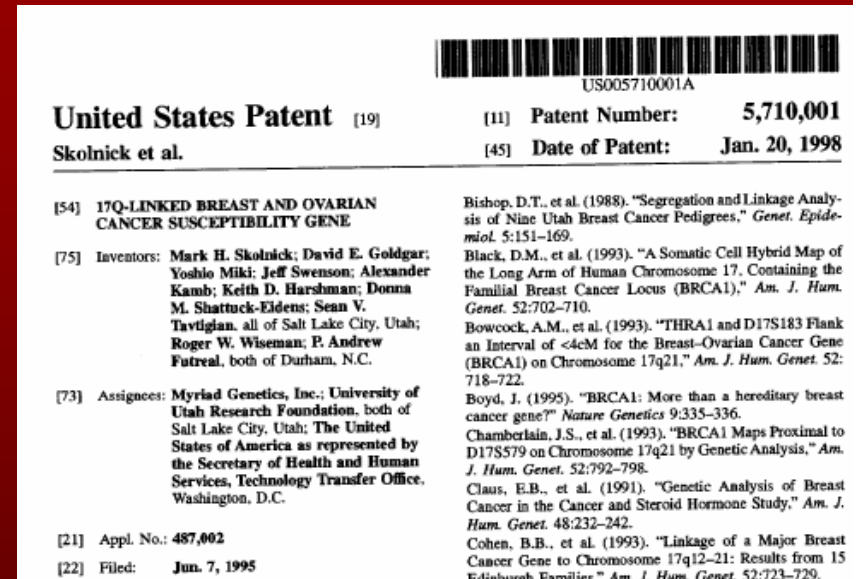
Privatization of upstream biomedical research in the United States may create anticommons property that is less visible than empty storefronts but even more economically and socially costly. In this setting, privatization takes the form of intel-





# Patent Example 2: U Penn and BRCA1 Testing

- Arupa Ganguly, at the University of Pennsylvania, was using an in-house test for BRCA1 genes in a multi-center study funded by the National Cancer Institute.
- Myriad Genetics holds the license for that test, and insisted that the tests be done through them, for a fee that Ganguly said would make their non-profit work unaffordable.





## Patent Example 2: U Penn and BRCA1 Testing

- “By flexing monopoly rights ... Myriad is able to dictate terms under which academic researchers may or may not perform their own tests on the company's patented genes and sometimes even determine which projects they can pursue. Physicians and geneticists say their academic freedom is being crimped by the limits imposed on them by patents....” (Blanton 2002)



## Patent Example 2: U Penn and BRCA1 Testing

- The increasing number of gene patents has resulted in genetic disease tests “being monopolized by a small number of providers,” and this “threatens to restrict research activities.” (Merz 1999)



## Patent Example 3: Allison Snow and Bt Sunflowers

- Allison Snow, Ohio State University, did field tests of Bt sunflowers



Source: Dalton 2002



## Patent Example 3: Allison Snow and Bt Sunflowers

- DuPont and Pioneer Hi-Bred hold the patent on Bt sunflowers and refused to allow Snow to do follow up studies, even with university funding.



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A DUPONT COMPANY



## Patent Example 4: Metabolite and Vitamin B

- Metabolite owns a patent (awarded to scientists at the University of Colorado and at Columbia) for a diagnostic test ascertaining whether a person is deficient in either B12 or folic acid.



## Patent Example 4: Metabolite and Vitamin B

- Claim 13: “assaying a body fluid for an elevated level of total homocysteine; and correlating an elevated level of total homocysteine in said body fluid with a deficiency of [B12] or [folic acid].”
- LabCorp was found guilty of direct infringement: “The record shows that physicians order assays and correlate the results of those assays, thereby directly infringing.”
- LabCorp was also found guilty of actively inducing others to infringe: “LabCorp publishes both Continuing Medical Education articles as well as a Directory of Services that are specifically targeted to the medical doctors ordering the LabCorp assays. These publications state that elevated total homocysteine correlates to [B12/folic acid] deficiency and that this deficiency can be treated with vitamin supplements. LabCorp’s articles thus promote total homocysteine assays for detecting [B12/folic acid] deficiency.”

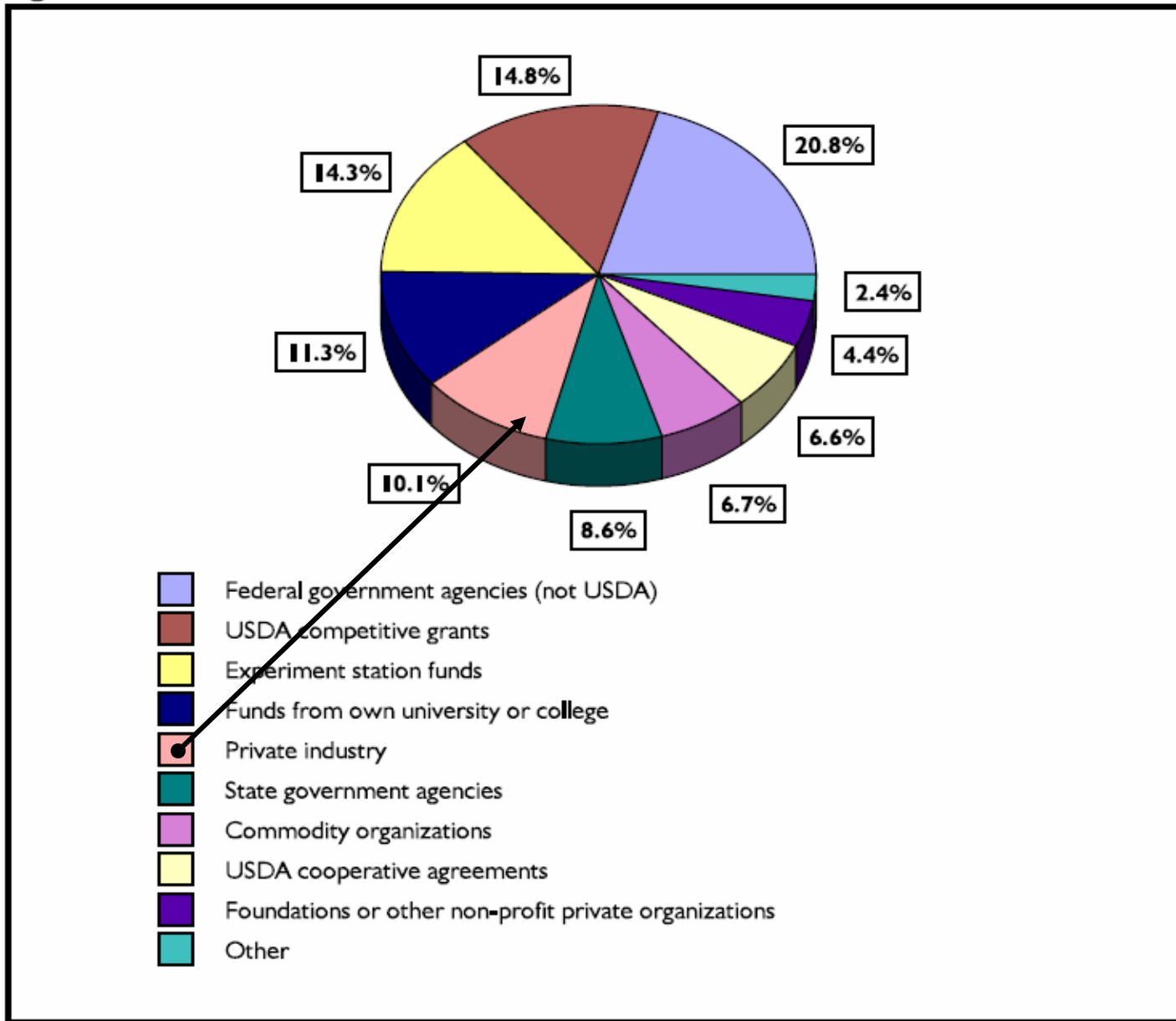


## Extent of Industry Funding

- In biomedical research (Bekelman et al., 2003):
  - 23-28% receive research funding from industry
  - 43% receive research-related gifts from industry
  - Industry's share of biomedical R & D investment was 32% in 1980 and 62% in 2000.
  
- In the life sciences (Blumenthal et al. 1996):
  - Industry provided 8.9% of research funds
  
- In the agricultural science (Goldberger 2005):
  - 45% had some (>1%) industry funding, totaling about 10% of the total



**Figure 3. Percentage Distribution for Research Funding Sources, U.S. Land-Grant Agricultural Scientists, 2005 \***



\* Respondents were asked about their funding sources over the past five years.

Source: Goldberger et al. 2005



## Impact of Industry Funding: Restrictions on Publication and Data Sharing

- Biotech faculty with industry support were five times as likely to need permission from their sponsor prior to publishing (Blumenthal 1992)
- Almost half of medical biotech companies reported that their agreements with universities “sometimes require withholding of data” and that more than half of those had required researchers to do so (Blumenthal 2002)
- 47% of biotech companies surveyed said that they required researchers to withhold data “longer than is necessary to file a patent” (Blumenthal 1996)



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## Impact of Industry Funding: Restrictions on Publication and Data Sharing

- “In multivariate analyses, male gender, participation in relationships with industry, mentors’ discouraging data sharing, receipt of formal instruction in data sharing, and negative past experience with sharing were significantly associated with either verbal or publishing withholding among either geneticists or [other life scientists]. (Blumenthal et al. 2006)



## Funding Example 1: Olivieri and Deferiprone

- Nancy Olivieri, at the University of Toronto
- Research funded by Apotex on deferiprone, a bivalent iron chelator





## Funding Example 1: Olivieri and Deferiprone

As you now [sic], paragraph 7 of the LA-02 Contract provides that all information whether written or not, obtained or generated by you during the term of the LA-02 Contract and for a period of three years thereafter, shall be and remain secret and confidential and shall not be disclosed in any manner to any third party except with the prior written consent of Apotex. Please be aware that Apotex will take all possible steps to ensure that these obligations of confidentiality are met and will vigorously pursue all legal remedies in the event that there is any breach of these obligations.

Excerpt from a letter dated May 24, 1996, from Dr. Michael Spino, Vice President of Scientific Affairs, Apotex Research Inc., to Dr. Nancy Olivieri.



## Funding Example 2: Dong and Levothyroxine

- Synthroid was the dominant preparation of levothyroxine, used to treat thyroid disease
- Betty Dong, at UCSF, was funded by the manufacturer of Synthroid, Flint Laboratories (later taken over by Boots Pharmaceuticals, Inc.), to study whether Synthroid was bioequivalent to 3 other preparations.
- In 1990, Dong had concluded her study and found that all 4 preparations were bioequivalent.





## Funding Example 2: Dong and Levothyroxine

- “When I inquired, Dr Dong explained to me that in the protocol/contract she had signed back in May 1988, there was a restrictive covenant which read: “All information contained in this protocol is confidential and is to be used by the investigator only for the conduct of this study. Data obtained by the investigator while carrying out this study is also considered confidential and is not to be published or otherwise released without written consent from Flint Laboratories, Inc.” They did not have this permission, and she had just been told by a UCSF attorney that because of this clause, the university advised her to withdraw the paper, saying it would not defend the authors if a suit was brought by Boots.” (Rennie 1997)





## Funding Example 3: Chapela and Maize Landraces

- September 2001: David Quist and Ignacio Chapela published in *Nature* that transgenic DNA had moved into maize landraces in the mountains of Oaxaca, Mexico.



Above, a sample of maize from one farmer's small fields in Oaxaca . The varieties represented here are called pinto (speckled), amarillo (mostly yellow) and negro (mostly black), which describe the colors of the kernels. Photo courtesy of Sol Ortiz-Garcia. Below, Professor



## Funding Example 3: Chapela and Maize Landraces

- Outspoken opponent of a five-year deal struck in 1998 with Novartis 
- Denied tenure in June 2003
- Michigan State University external review



## Problematic Funding Examples

- Funding Example 1: Olivieri and Deferiprone
- Funding Example 2: Dong and Levothyroxine
- Funding Example 3: Chapela and Maize Landraces



## The Consequentialist Account

- The value of academic freedom derives from the value of academic research itself.
- Academic research is important because it results in knowledge and technology that promote the common good.
- Restrictions on academic freedom are therefore to be condemned because they hinder the pursuit of the common good.



## The Consequentialist Account

- “Institutions of higher education are conducted for the common good....The common good depends upon the free search for truth and its free exposition.” (AAUP 1940)



## Rights-Based Accounts

- Rights-based Accounts: Academic freedom is important because it is something to which individual academics have a right.
- “The classical theory of academic freedom, and the heart of any theory of academic freedom, is that professors should have the right to teach, conduct research, and public their research without interference....” (Searle 1971).
- Derived from more general civil rights, or a distinct right grounded in the special nature of academia.



## Restricted Focus

- Focusing only on:
  - those aspects of academic freedom directly related to individual faculty research and publication



## What Really Matters from a Consequentialist Perspective

- A beneficial enabling restriction: a restriction that forms an integral part of a larger system that enables more academic research on balance and thereby does a better job of promoting the common good
- A harmful restriction: a restriction that is not a beneficial enabling restriction
- From a consequentialist perspective, objections to AIRs are inconclusive if they leave open the possibility that the resulting restrictions are beneficial enabling restrictions.





## Patents as Beneficial Enabling Restrictions

- Patents are intended to be beneficial enabling restrictions.

“To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.” (U.S. Constitution, article 1 § 8)



## Patents as Beneficial Enabling Restrictions

- A patent grants the assignee a limited monopoly (even against independent inventors)
- Increases expected profits, making potential investors more willing to provide funding.
- More funding results in more inventions and discoveries which, in turn, enable research that might have not been possible otherwise.



## Patents as Beneficial Enabling Conditions

- Patents are published, making public the details of how to make the invention, which increases the spread of knowledge and research opportunities for others.



## Potrykus and Golden Rice Revisited from a Consequentialist Perspective

- Potrykus: "At that time I was much tempted to join those who radically fight patenting. Fortunately I did a bit of further thinking and became aware that "Golden Rice" development was only possible because there was patenting. Much of the technology I had been using was publicly known because the inventors could protect their right. Much of it would have remained secret if this had been the case." ("The Golden Rice Tale")



## U Penn and BRCA1 Testing Revisited from a Consequentialist Perspective



- Mark Skolnick: "If it's not patented, you won't get some group to spend money to develop it, and you won't get a high-quality, inexpensive test." (Brown and Kleiner 1994)



# Patenting and Publishing

J. Neurochem. 72, 1283–1293, 1999

J. Pharm. Exp. Ther. 293, 1091–1098, 2000

Brain Res. 854, 257–262, 2000

J. Biol. Chem. 276, 708–714, 2001

J. Pharm. Exp. Ther. 296, 57–63, 2001

Neurosci. Lett. 307, 167–170, 2001

J. Mol. Neurosci. 19, 167–170, 2002

J. Mol. Neurosci. 18, 37–45, 2002

Brain Res. 144, 83–90, 2003

Proc. Natl. Acad. Sci. U S A. 100, 8543–8, 2003

Peptides 24, 1413–1423, 2003

J. Mol. Neurosci. 14, 61–68, 2000

J. Mol. Neurosci. 15, 137–145, 2000

Reg. Peptides 96(1–2), 39–43, 2000

Trends Neurosci. 24, 700–705, 2001

J. Pharm. Exp. Ther. 297, 774–779, 2001

J. Pharm. Exp. Ther. 303, 110–116, 2002

Stroke. (4):1085–92, 2002

Drug Dev. Res. 56:475–481 (2002)

J. Mol. Neurosci. 20, 315–322, 2003

Neuroreport. 14, 481–484, 2003

Neurosci. Lett. In press

Source: Spier, "Exploring Patenting and Licensing Policy for Proteomics: A Small Biotech Perspective"



## Fair enough, but...

- GAO survey: “many institutions may be spending more on obtaining and licensing patents than they are realizing in revenues” (Blumenthal 1992)
- Fear of litigation can have a chilling effect on research.
- Patents may enable publications in some cases, but they delay and prevent publications in others.
- Commercial distribution of invention would amount to disclosure in many cases, even without a patent



## Need Data on Net Effect of Patents

- Need more empirical data regarding the impact of patents on enabling and preventing academic research under the current system and also under whatever alternative system would be implemented





## Need Data on Net Effect of Patents

- Fritz Machlup (1962, p. 176): “[t]he absence of any empirical evidence for either the claim or its denial that the patent system is an effective promoter of inventive research—and thus of the production of socially new technological knowledge—is most frustrating.”



## Need Data on Net Effect of Patents

- Richard Posner (2002, p. 12): “For all we know, too many resources are being sucked into the creation of new biotechnology, computer software, films, pharmaceuticals, and business methods because the rights to these different forms of intellectual property have been too broadly defined. Unfortunately, the empirical problems are acute—and little progress has been made as yet toward their solution. We urgently need more empirical evidence. The task is daunting, for it requires that we be able to estimate both the social gains from additional intellectual property of different types and the social costs of trying to induce the creation of the additional intellectual property by means of adjustments in the regime of intellectual property rights .”



## Need Data on Net Effect of Patents

- 2004 meeting of the National Academies' Committee on Intellectual Property Rights in Genomics and Protein-Related Research (National Academies 2004)
  - Shirley Tilghman, chair: "there is a lot of urban legend out there about the impact of patent policy... but [there] are few data."
  - Corey Goodman, chair of the National Academies' Board on Life Sciences: "you've got anecdotes, and you wonder if there is data"



## Restrictions Tied to Industry Funding as Beneficial Enabling Restrictions

- **Additional** funding, even with restrictions, could easily enable more academic research than it prevents
- Even data publication restrictions that might result in patient harm, as in the Olivieri case, are difficult to assess



## Fair enough, but...

- But what impact would bans on certain kinds of restrictions (e.g. gag rules, time limitations) have on the level of industry funding?
- Does increased industry funding provide an excuse or incentive for reductions in state and federal funding?



## Data on Net Effect of Restrictions Due to Industry Funding

- "Despite increasing awareness about the potential impact of financial conflicts of interest [arising from industry funding and consulting] on biomedical research, no comprehensive synthesis of the body of evidence relating to financial conflicts of interest has been performed."  
(Bekelman et al. 2003)



## Data on Net Effect of AIRs on Agricultural Biotechnology

- “[S]cientific knowledge about UIRs [university-industry relationships] in agricultural biotechnology is scant. Baseline information about the nature and functioning of these UIRs is incomplete. Society is largely “flying blind” on one of the most important revolutions in our agricultural research system. Without improved data and more research, policy actions to reduce possible problems and obtain the largest social net benefits from the UIRs are subject to considerable guesswork.” (Pew 2002)



## The Challenge from the Consequentialist Perspective

- Despite the existence of ample data that document specific restrictions and patterns of restrictions that result from AIRs, most claims about the *net* effect that AIRs have on academic research suffer from severe, and presently unresolved, epistemological problems.
- *A fortiori*, there is little reason to believe that AIRs constitute harmful restrictions as opposed to beneficial enabling restrictions.





## The Challenge from the Consequentialist Perspective

- N.B.: any defense of AIRs on the grounds that they have a positive overall effect on academic research is equally undermined.
- As Machlup (1962, p. 176) said with respect to patents, "Advocates of patent protection have for centuries propounded the faith in this institution, and their statements admit of not an iota of doubt. They may well have the truth—but faith alone, not evidence, supports it."



## The Right to Academic Freedom

- The right to academic freedom "is a liberty marked by the absence of restraints or threats against its exercise," but it does not include "an enforceable claim upon the assets of others." (Van Alstyne 1972)
- A person P has a liberty to engage in an activity A if and only if (1) no other person has any claims against P that P not engage in A, and (2) P has a claim against others that they not coercively interfere with P's performance of A.



## The Right to Academic Freedom

- A person P has a liberty to engage in an activity A if and only if (1) no other person has any claims against P that P not engage in A, and (2) P has a claim against others that they not coercively interfere with P's performance of A.
- Example: I have a liberty to park in an open, public parking spot.



# The Scope of the Right to Academic Freedom

- Broad: All academic research
- Narrow: Standards of “reasonable care”



## The Scope of the Right to Academic Freedom

- If an academic researchers' right to academic freedom included the right to do academic research that inflicted involuntary harm, then:
  - That researcher would have a liberty to engage in that research, but its being a liberty implies that:
    - The subjects do not have a claim that the researcher not involuntarily harm them, but:
      - They do.



# The Scope of the Right to Academic Freedom

- Broad: All academic research
- Narrow: Standards of “reasonable care”
- Narrower Still: Fails to include a right to any claim-infringing research whatsoever



## The Challenge for a Rights-Based Account

- Patents confer claims
- Contracts accompanying industry funding confer claims
- The right to academic freedom doesn't include a claim on the resources necessary for research
- From a rights-based perspective, many of the problematic restrictions restrict activities that are not protected by the right to academic freedom



## Overcoming the Challenge

- Some criticisms are left unscathed:
  - UPenn researchers were using a test for BRCA1 that they developed *independently*
  - The data Olivieri wanted to publish was not covered by a confidentiality agreement
  - Chapela had not waived his right to academic freedom





## Overcoming the Challenge

- Even if industry has claims, enforcement of those claims can still be unethical and prohibited:
  - If I agree as a research subject to be in 6 month long sleep study requiring confinement to the sleep lab, then the researcher has a claim against me that I not leave the sleep lab during that time, and I am no longer at liberty to leave.
  - But if I change my mind after 3 months, the researcher cannot forcibly make me stay.



## Overcoming the Challenge

- Limiting the scope of the right to academic freedom is itself problematic
  - Be more judicious in granting claims that limit the scope of academic researchers' rights to academic freedom
  - International Committee of Medical Journal Editors "Uniform Requirements for Manuscripts Submitted to Biomedical Journals"
  - NIH Guidelines (<http://ott.od.nih.gov>)



## Overcoming the Challenge

- Avoid Unnecessary Exclusivity in Licensing
  - Ensure Appropriate Scope
  - Ensure Expeditious Development
  - Address Public Health Benefits



# Overcoming the Challenge

## EXAMPLE – HUMANITARIAN USE RESERVATION

### ■ 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, and (b) the use of Invention/Germplasm for Commercial Purposes, including the use and production of Germplasm, seed, propagation materials and crops for human or animal consumption, 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 outside of the Developing Country where a commercial licensee has introduced or will introduce a product embodying the Invention/Germplasm. For avoidance of doubt, not-for-profit organization and/or the Developing Country, or any individual or organization therein, may export the Germplasm, seed, propagation materials or crops from the Developing Country of origin to other Developing Countries and all other countries mutually agreed to by Licensor and Licensee.**



## Overcoming the Challenge

### ***WHEAT WORKER'S CODE OF ETHICS***

This seed is being distributed in accordance with the 'Wheat Workers' Code of Ethics for Distribution of Germplasm', developed and adopted by the National Wheat Improvement Committee on 5 November, 1994. Acceptance of this seed constitutes agreement.

1. The originating breeder, institution, or company has certain rights to the unreleased material. These rights are not waived with the distribution of seeds or plant material but remain with the originator.
2. The recipient of unreleased seeds or plant material shall make no secondary distributions of the germplasm without the permission of the owner/breeder.



# Overcoming the Challenge

- Professional codes and mentoring students



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## CODE OF SCIENTIFIC ETHICS

for the United States Department of Agriculture, Agricultural Research Service

I dedicate myself to the pursuit and promotion of beneficial scientific investigation, consistent with the mission of the Agricultural Research Service.

I will never hinder the beneficial research of others.

I will conduct, discuss, manage, judge, and report science honestly thoroughly, and without conflict of interest.

I will encourage constructive critique of my personal science and that of my colleagues, in a manner that fosters harmony and quality amid scientific debate.



# Overcoming the Challenge

## ■ Professional codes and mentoring students

### *Code of Ethics*

### *American Society for Biochemistry and Molecular Biology*

*(approved by the ASBMB Council in January 1998)*

Members of the ASBMB are engaged in the quest for knowledge in biochemical and molecular biological sciences with the ultimate goal of advancing human welfare. Underlying this quest is the fundamental principle of trust. The ASBMB encourages its members to engage in the responsible practice of research required for such trust by fulfilling the following obligations.

#### *In fulfilling OBLIGATIONS TO THE PUBLIC, it is EXPECTED that:*

investigators will promote and follow practices that enhance the public interest or well-being;

investigators will use funds appropriately in the pursuit of their research;

investigators will follow government and institutional requirements regulating research such as those ensuring the welfare of human subjects, the comfort and humane treatment of animal subjects and the protection of the environment;

investigators will report research findings resulting from public funding in a full, open, and timely fashion to the scientific community; and

investigators will share unique propagative materials developed through publicly-funded research with other scientists in a reasonable fashion.



# Code of Ethics for Members of the ASPB

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One of the objectives of the Alberta Society of Professional Biologists is to promote high standards of professional competence and ethics in its membership. Accordingly, a Code of Ethics for the Society has been adopted by the Society to serve as a guide for members of the Society in their practice of professional biology. Acceptance of this code of ethics is an important part of membership in the Alberta Society of Professional Biologists. Members of the Society are encouraged to become familiar with the Code of Ethics printed in this brochure.

## 1. General Responsibilities

The Code of Ethics of the Alberta Society of Professional Biologists requires members to exhibit competence and integrity in all aspects of the practice of professional biology.

A professional biologist will:

- Conduct and practice professional biology in accordance with the laws of Alberta and Canada.
- Bring to the attention of authorities and the Directors of the Society any activity in the practice of professional biology which he is convinced is illegal or incompatible with the ethics of the Society.
- Complete, sign or support only those projects and reports which are considered to be in conformity with standards established by the Directors of the Society.
- Attempt to convey to the public at large, as well as to other professions, an understanding of the basic concepts of biological sciences and its practice as related to the natural environment and the public welfare.
- Accept full responsibility for the results and conclusions (including all reports) of biological investigations for which he or she is principally responsible, and refuse to allow his or her name to be associated with reports or conclusions of investigations which have been altered in such a manner as to imply substantially different conclusions than those originally stated.
- Refuse to carry out any work for which he or she is not competent to perform by virtue of training and experience.
- Refuse to enter into any agreement with any employer or client to practice professional biology in a manner inconsistent with any of the foregoing.





## Overcoming the Challenge

- Appeal to the rights and interests of others
  - Apotex was causing involuntary harm to patients
  - Society's long-term interest in pursuing basic research



## Overcoming the Challenge

- Appeal to the rights and interests of others
  - Society's long-term interest in objective evaluators of industry products and practices
    - 51% of industry funded trials on calcium channel blockers had a pro-industry conclusion; 0% of non-industry funded trials (Bekelman et al. 2003)
    - 94% of industry funded trials on effects of second-hand smoke had a pro-industry conclusion; 13% of non-industry funded trials (Bekelman et al. 2003)



## Overcoming the Challenge

- Appeal to the rights and interests of others
  - Academia's interest in openness and sharing
    - Biotechnology faculty with industry support were four times more likely to have conducted research that resulted in "information kept secret to protect its proprietary value" (Blumenthal 1992)
    - 11% of faculty members with industry support had refused requests to share research results or materials; 5.8% without industry support (Blumenthal 1996)



## The Take-Home Message

- AIRs frequently result in restrictions on academic research.
- The academic community believes that many of those restrictions are especially egregious, and criticizes them on the grounds that they constitute restrictions on academic freedom.
- Establishing the soundness of those criticisms is challenging, on both empirical and conceptual grounds.
- But in spite of those challenges, many of the examples are truly problematic, and academic freedom still plays an important conceptual role in explaining why those restrictions are unacceptable.



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