University-Industry Relationships: Framing the Issues for Academic Research in Agricultural Biotechnology

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Proceedings from an expert workshop sponsored by the Pew Initiative on Food and Biotechnology and the U.S. Department of Agriculture's Initiative for Future Agriculture and Food Systems Project "Public Goods and University-Industry Relationships in Agricultural Biotechnology"





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University-Industry Relationships: Framing the Issues for Academic Research in Agricultural Biotechnology

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Preface

The relationships between academic researchers and the agricultural biotechnology industry changed after important legal and legislative actions were taken in the 1980s. Firms entered into agreements with public and private universities, providing financial and other resources in return for research and product testing performed by the universities. Some believe the agreements encourage innovation and early application of new technologies that benefit the agricultural sector, consumers and the environment. Others raise concerns, for example, that the greater emphasis on commercial applications diverts academic researchers away from research and technology development that may have significant public benefit but little commercial potential.

Despite the assertions, both pro and con, the issues surrounding university-industry relationships (UIRs) in agricultural biotechnology are not sharply defined. This lack of clarity reflects, in part, the short period since collaborations between universities and agricultural biotechnology firms emerged. To start filling the information gap, the team from a project funded by the U.S. Department of Agriculture entitled "Public Goods and University-Industry Relationships in Agricultural Biotechnology"¹ joined with the Pew Initiative on Food and Biotechnology² to co-sponsor an expert workshop.³ University scientists, administrators and technology transfer officers, representatives from industry and nonprofit organizations, and government officials were assembled to identify salient researchable issues involving UIRs in agricultural biotechnology and the academic research enterprise.⁴

This report does not attempt to frame all issues necessary to understand the net social benefit of UIRs in agricultural biotechnology. Rather, it focuses primarily on the effects of UIRs on academic basic and applied research in the area. This focus is the central thrust of the U. S. Department of Agriculture funded project noted above. A central question is whether the academic-industry relationships alter the traditional university roles of conducting basic and applied research on issues of public interest that will not be addressed by industry.

This report presents three types of information to provide context and frame the salient research questions associated with UIRs:

- Overviews of research findings on UIRs in general,
- Insights from speakers, and
- Workshop participants' suggestions.

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¹ For project information, see http://www.agri-biotech.pdx.edu. The authors appreciated the support of Dr. David Holder of USDA's Cooperative State Research, Education, & Extension Services in conducting the workshop.

² For information on the Pew Initiative, see http://pewagbiotech.org. Michael Rodemeyer, Director of the Pew Initiative and Skip Stiles, Consultant to the Pew Initiative, played key roles in designing the workshop.

³ The workshop program appears in appendix A.

⁴ Appendix B lists workshop participants.

The USDA project will ultimately address some of the research questions identified herein. However, much more research is needed to understand the diversity of UIRs in agricultural biotechnology, the motivations of the parties involved, and the implications of the collaborations for producers, consumers, industry, government and others in society.

The authors are grateful to workshop speakers and participants for sharing their valuable insights on this complex set of issues, as well as those people who were involved in the review of the proceedings, but remain solely responsible for the contents of this report.

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Executive Summary

University-industry relationships (UIRs) have emerged as a key force in the development and commercialization of agricultural biotechnologies. A growing number of scientists in public and private universities are involved in close working relationships with commercial firms. The relationships offer potential benefits to both parties, and are encouraged by many federal and state policies. From the perspective of academic researchers, collaborating with industry provides an additional source of research funding, access to proprietary technology and research tools, and an opportunity to develop and bring technologies to the marketplace. For companies, collaboration provides them with access to scientific talent and cutting edge science. Depending upon their structure and implementation, however, UIRs may also present risks. For example, concerns have surfaced in some situations about the influences of UIRs on the traditional roles of universities in conducting basic research, encouraging the open exchange of scientific information, and applied research and technology development that has public benefit but not commercial viability. However, the absence of information about the nature and operation of UIRS in agricultural biotechnology makes it difficult to assess their impacts on these roles.

This report is intended to improve our understanding of UIRs in agricultural biotechnology, and to frame salient research questions about their effects on the academic research enterprise. It does not address the full set of issues necessary to assess the net social benefit of the academic-industry relationships, including any benefits, risks and costs for producers, consumers, and the environment. The report's discussion presents research findings about UIRs in general, as interpreted by the authors, as well as the insights gained from speakers and participants in a workshop held last year to identify the salient research questions. From the workshop, three key areas for research emerged and are presented in chapters two through four of this report:

- BUILDING A BASELINE Insufficient information exists to understand the range of UIRs in agricultural biotechnology.
- EFFECTS ON UNIVERSITY SCIENTISTS' RESEARCH AGENDAS UIRs bring new resources and opportunities to research programs, but also pose risks.
- INTELLECTUAL PROPERTY AND TECHNOLOGY TRANSFER The intellectual property system, although workable, can be costly and may hinder innovation.

We hope the report stimulates research that will assist government, industry, and universities in designing and implementing policies to foster UIRs in agricultural biotechnology that benefit each party and also contribute to the public good.

Building a Baseline

A rich literature describes UIRs in other sectors (Business-Higher Education Forum 2001), but comparable information does not exist for agricultural biotechnology. For example, the percentages of UIRs in agricultural biotechnology that focus on basic research versus those that pertain to product performance testing are unknown. Without baseline information, it is impos-

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sible to analyze how faculty may change their research agendas due to industry relationships, while accounting for the influences of other forces, for example public funding patterns. Workshop participants underscored the need for a national database that captures the diversity of the relationships in order to facilitate future analyses of their effects. The group framed four main sets of questions to guide the collection of baseline information (see Table 1).

Table 1 • Key Researchable Issues—Building a Baseline

1. How many UIRs in agricultural biotechnology exist?

- How are the agreements distributed over public land-grant, public non-land-grant and private universities?
- How are the agreements distributed over different-sized universities?
- How are the agreements distributed over different-sized biotechnology firms?

2. What are the major types of research that are part of UIRs?

- Do the universities conduct basic⁵ or applied⁶ research as part of the agreement?
- Are there differences in the participation of land-grant and non-land-grant public universities and private universities in UIRs?
- How many of the agreements involve product performance testing?
- What fields of agricultural biotechnology are more likely to be involved in UIRs?

3. What universities participate in which types of UIRs?

- What percentage of a university's research budget is from UIRs involving agricultural biotechnology?
- Do scientists from larger universities collaborate more with larger companies?
- Do scientists from smaller universities collaborate more with biotech start-up firms?

4. What types of firms collaborate with universities in which types of UIRs?

- Does the stage of firm development, e.g., large and mature or small start-up, influence the type of research?
- Do some types of biotechnology firms form agreements that stress product performance testing more than others?
- How many start-up firms owned by university faculty members collaborate with their university?

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⁵ Basic research is generally defined as "...research directed toward increases in knowledge or understanding of the fundamental aspects of phenomena and of observable facts without specific application toward processes or products in mind. For the industry sector, basic research projects are defined as original investigations for the advancement of scientific knowledge which do not have specific commercial objectives, although they may be in fields of present or potential interest to the reporting company" (NSF 1994).

⁶ Applied research is generally defined as "...research directed toward gaining knowledge or understanding necessary for determining the means by which a recognized and specific need may be met. The applied research definition for the industry sector is modified to include research projects which represent investigations directed to discovery of new scientific knowledge and which have specific commercial objectives with respect to either products or processes" (NSF 1994).

Effects on Scientists' Research Agendas

Analyses of UIRs outside agricultural biotechnology have identified benefits and risks for university researchers. For example, surveys have found that scientists with industry support publish at higher rates, patent more frequently, participate in more administrative and professional activities, and earn more than their colleagues without such support. Research also suggests that UIRs pose risks to traditional university values, such as the open communication between scholars, the unhampered pursuit of knowledge, and the full and timely disclosure of research findings. The surveys generally have not addressed more specific effects on the scientists' research programs.

Three academic scientists at the workshop described both the more and less favorable aspects of their relationships with the agricultural biotechnology industry. Although larger forces are shaping UIRs in general, the three scientists emphasized the need to understand the "individuality" of UIRs. For example, the effect on the "publicness" of research outputs derived from industry relationships varied considerably among these scientists. Workshop participants identified questions in two areas of research for this issue (see Table 2).

Intellectual Property and Technology Transfer

Intellectual property (IP) and technology transfer (TT) can be controversial issues in university-industry research collaborations. The 1980 Diamond v. Chakrabarty U.S. Supreme Court decision and the 1985 Ex parte Hibberd et al. opinion made it possible to patent live artificially-engineered organisms, including plants and animals. Also, the 1980 Bayh-Dole Act changed the possibilities and incentives for universities to retain title to inventions, including those in agricultural biotechnology, funded wholly or in part by federal research funds. Supporters and critics of UIRs alike believe these actions have transformed the academic biological science landscape in fundamental ways by placing more emphasis on creating and managing intellectual property.

Considerable research has been conducted on IP and TT issues, but not in relation to UIRs in agricultural biotechnology. This research has found that both firms and universities benefit from the intellectual property associated with UIRs. Specifically, firms whose scientists collaborate with top university scientists tend to earn more patents and more highly cited patents than do other firms. Academic scientists involved in UIRs tend to patent more frequently, as noted above. A benefit for universities is demonstrated by the approximate fivefold increase in annual university revenues from all research licensing agreements observed during the 1990s. Notably, despite this increase, licensing revenue remains a very small percentage of total university support, and less than half of universities realize enough royalty income to cover the costs of technology transfer offices.

Critics believe the quest for IP and TT by some universities will restrict the open flow of scientific information, raise the cost of research through licensing agreements, and hinder the development of new agricultural biotechnology products with the potential for public benefits but without commercial viability. At the workshop, technology transfer officials from a major university and a global nonprofit organization offered some ideas about how to avoid overly restrictive patents and licenses. Given this backdrop, workshop participants identified questions in three areas of research to illuminate the IP and TT issues (see Tables 3, 4, and 5).

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Table 2 - Hey Researchable Issues—Effects on Scientists' Research Agendas

Influences on research topic and direction

- 1. What are the major factors that influence academic scientists as they set research agendas?
 - Do academic scientists who collaborate with industry do more applied than basic research than their peers who do not have industry support?
 - How does access to proprietary information and technologies from industry affect a scientist's choice of research topics?
 - Does industry funding exert more leverage on scientists' research agendas than federal government or other funding?
- 2. Does the university tenure and reward system affect a scientist's incentive to form industry relationships and their choice of research topics?
 - Does the scientist's rank (assistant, associate or full professor) influence the research direction or choice of funding?
 - Is there an institutional mechanism, such as criteria for attaining tenure, that encourages scientists to pursue certain forms of research funding?
 - Do incentives exist to research areas that are not funded by the private sector?
 - In terms of university peers, is private or public funding more relevant to a scientist's career success?
- 3. Does the existence of an Office of Technology Transfer (OTT) affect an academic scientist's research agenda?
- 4. To what extent does the opportunity to participate in a start-up company influence an academic scientists' research agenda?

Effects of industry funding

- 1. Have academic scientists allowed their work plans/research objectives/publications to be changed by industry funding?
- 2. Does industry funding have a larger effect on scientists' research agendas than federal funding?
 - Does demand from industry for certain types of research enhance or distort the scientist's research agenda?
- 3. Do academic scientists with private funding and public funding have similar definitions of the public good?
- 4. What is the "correct" balance between publicly funded versus privately funded research?
- 5. Does collaboration with industry affect the types of scientific outputs, e.g., the types of traits of genetically engineered crops?
- 6. Has basic research shifted to private sector? How much basic research is patentable?

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Table 3 - Hey Researchable Issues—Intellectual Property and Technology Transfer

Decrease in free exchange, barriers, and delays

- 1. How often are university scientists denied access to research materials or information?
- 2. Is there a decrease in the free exchange of knowledge and information, and if so, what force(s) are driving it?
- 3. Are publication delays due to intellectual property issues prevalent?
 - How should the delays in discovery and innovation from intellectual property issues be measured?
- 4. How many crops (transgenic and otherwise) have been developed but have not been used?
 - What are the barriers to commercialization?
 - Do universities support defensive or blocking patents? How do UIRs affect communicaton among colleagues in the scientific community?
- 5. What has been the trend since Bayh-Dole in terms of number of material transfer agreements?
- 6. Do universities allow material transfer agreements with reach-through privileges?
- 7. What are the costs to TT personnel to university scientists (including their time) in negotiating intellectual property and technology transfer arrangements?
 - How can these costs be reduced?

Table 4 - Hey Researchable Issues—Intellectual Property and Technology Transfer

Office of technology transfer and performance measures

- 1. What are the costs and revenues of university technology transfer operations and IP transactions?
- 2. Where does the money come from to finance the search for IP in universities?
- 3. What is the range of resources that different universities dedicate to IP?
- 4. What drives patenting and licensing at universities? Who is doing the marketing of universities' patents?
- 5. What are the performance measures for offices of technology transfer?
- 6. What are the appropriate financial returns to offices of technology transfer, faculty, the private sector, or public interest?

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Table 5 - Hey Researchable Issues—Intellectual Property and Technology Transfer

- 1. Which sectors of society are helped by the various types of IP created in industry and universities?
 - What are the deficiencies in our society that agricultural biotechnology might be used to address?
 - What is being done for the public good? What tools or products have had environmental benefits or fostered economic development?

2. What sort of patents are being generated at universities?

- How many patents are for products?
- How many patents are for processes?
- What is the view of faculty on patenting?
- What are the costs and benefits of patenting?

3. Does a university's funding portfolio affect it's patent licensing practices?

- Is the proportion of a university's patents falling under various technology domains affected?
- Are higher levels of industry funding associated with more exclusive licensing of university intellectual property?

4. Are university licenses put to the best possible (highest) uses?

- Do exclusive licenses have "teeth" or milestones built into them to ensure that revenues are collected or technology is used and not shelved?
- What are the global impacts of licensing agreements?
- When universities are granting exclusive licenses, do they include humanitarian exclusions?
- 5. Is intellectual property pooling feasible?
- 6. Have scientists chosen not to license technologies from industry?

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Conclusion

The historic pattern of UIRs in agriculture is being transformed, perhaps with profound implications for the future path of science and technology development. The authors drew three overarching conclusions from the workshop. First, scientific knowledge about UIRs in agricultural biotechnology is scant. Baseline information on 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 benefit from the UIRs are subject to considerable guesswork.

Second, what little is known about UIRs in agricultural biotechnology, suggests the framework for these relationships varies from case to case. They often depend on individual relationships between university and industry scientists and their specific research objectives. While the university scientist's desire to publish papers and the firm's desire to make a profit may be common motives for developing UIRs, the "individuality" of UIRs challenges our analytical ability to understand the factors that motivate UIRs formation as well as their impacts via broad general theories. The diversity makes for a rich area of investigation that requires multidisciplinary approaches, combining sociology, economics, and biology. The lack of "standardization" of UIRs also may introduce risks for some universities, firms, and agricultural sectors. For example, universities with less ability to negotiate favorable contract terms with industry may enter agreements that give firms exclusive licenses to the discoveries. For industry, some firms face the risk that university researchers may not deliver products in a timely fashion. Additionally, innovations for some agricultural sectors may be neglected by university-industry collaborations because markets for their products hold small potential commercial returns.

Third, mirroring the diversity in the relationships, the effects of the UIRs on technology innovation and the subsequent social, economic, and environmental effects are varied as well. Because UIRs are embedded in larger university, industry, and government institutional and policy settings, it is necessary to examine their performance within this larger complex system. For example, at the workshop's close, participants emphasized that appropriate government research policy and funding are crucial to balancing and complementing UIRs in agricultural biotechnology.

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Chapter 1. Introduction

University-industry relationships (UIRs) have emerged as a key force in the development and commercialization of agricultural biotechnologies. Many scientists in public and private universities are involved in close working relationships with firms. The relationships offer potential benefits to both parties, and are encouraged by many federal and state policies. From the perspective of academic researchers, collaborating with industry provides an additional source of research funding, access to proprietary technology and research tools, and an opportunity to develop technologies and bring them to the market. For companies, collaboration with academic researchers provides them with access to scientific talent and cutting edge science that the company could not duplicate on its own.

At the same time, industry-university research collaborations also present risks. For companies, the primary risk is that the investment fails to provide the kind of scientific return hoped for. For universities, concerns have been expressed about the effect of such relationships on the traditional roles of universities in conducting basic research, encouraging the open exchange of scientific information, and developing technologies that could provide public benefits without necessarily being concerned about commercial viability.

The industry support for academic research on genetically modified plants and animals⁷ has intensified the debate about the benefits and risks of such alliances. Three questions lie at the heart of this debate:

- 1. How do industry relationships affect the research agendas of academic scientists?
- 2. What are the effects of UIRs on intellectual property and licensing?
- 3. Do relationships with industry compromise or complement the role of universities to deliver public goods and services that are unlikely to be developed by market forces because firms cannot collect adequate revenues to cover their costs?

To date, little dispassionate analysis has been conducted to understand the forces shaping academic-business partnerships in agricultural biotechnology and their effects. Both those who support and those who oppose UIRs often cite anecdotal evidence and best or worst-case scenarios to support their perspectives. For example, supporters may point to a key discovery made possible through a UIR, but that does not imply all collaborations yield positive out-comes. What we lack is a systematic analysis of the variety of UIRs, the social, economic, and technological forces driving them, and a careful consideration of the significance of the consequences for industries, universities, and society in general.

The stakes of making poorly informed decisions about UIRs are high. The development of agricultural biotechnologies through UIRs may increase the flow of innovative products that increase agricultural productivity, lower consumer food prices, reduce some environmental

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⁷ Genetically modified or engineered organisms refer to crops and animals manipulated by molecular genetic techniques to exhibit new traits. Transgenic crops, the most commercially important subset, are genetically modified organisms containing novel genetic material (DNA) derived from an organism other than the parents or in addition to the parental genetic material. For example, soybeans genetically engineered for resistance to the synthetic pesticide glyphosate are a transgenic crop due to the introduction of a bacterial gene.

impacts associated with agricultural practices, and provide other benefits. UIRs also introduce risks and potential costs for society, including less academic research on 'public good' issues with findings made widely accessible to all potential users. A full analysis of the social benefits, risks and costs of UIRs would investigate all of the potential benefits, risks and costs to characterize the tradeoffs involved. That ambitious and worthy task is beyond the scope of this report. This discussion is more modest and focuses primarily on the effects of UIRs on the academic research enterprise, for example, their impacts on the traditional university roles of providing basic and applied public research on issues that otherwise would not be addressed by industry. That focus derives from the central objective of a U.S. Department of Agriculture funded project "Public Goods and University-Industry Relationships in Agricultural Biotechnology" that co-sponsored the workshop. If industry support is altering academic agricultural biotechnology research in ways that neglect such public goods, for example drought-tolerant plants that lessen community water demands, then the technology is at risk of failing to fulfill its potential for social benefits. Alternatively, if university-industry alliances are not exerting such influences and are contributing to public goods, policy restrictions on UIRs may inappropriately limit the technology's social benefits.

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Bringing the researchable issues into sharper focus

The primary purpose of the workshop was to identify the most salient researchable issues involving UIRs in agricultural biotechnology. Participants used three types of information to inform their selection of the key issues. First, the USDA-funded project team prepared an overview of findings from the literature on UIRs in general to set the context. Second, a range of invited speakers shared their diverse perspectives. Third, participants separated into five smaller groups and, drawing from their experiences and the workshop discussions, discussed and identified the most salient researchable questions. In a facilitated process, each group addressed (1) the effects on faculty research agenda, (2) the effects on intellectual property ownership and licensing, and (3) other aspects of the university-industry research system. Each group consisted of members representing the five types of participants: academic scientists, university administrators and technology transfer officers, representatives from industry, representatives from nonprofit organizations, and government officials.

This report summarizes the information from the workshop –including: (1) the general research findings on UIRs; (2) insights from invited speakers; and (3) the participants' suggestions in an attempt to build an improved understanding of the key aspects of UIRs in agricultural biotechnology, and to frame salient research questions in the following areas:

- BUILDING A BASELINE Insufficient information exists to understand the range of UIRs in agricultural biotechnology.
- EFFECTS ON UNIVERSITY SCIENTISTS' RESEARCH AGENDAS UIRs bring new resources and opportunities to research programs, but also pose risks.
- INTELLECTUAL PROPERTY AND TECHNOLOGY TRANSFER The intellectual property system, although workable, can be costly and may hinder innovation.

A strong message emerged at the close of the workshop that appropriate government research policy and funding are crucial to balancing and complementing UIRs in agricultural biotechnology.

Chapter 2 · Building a Baseline

2.1 Lessons from Literature

Case study and anecdotal information suggest UIRs in agricultural biotechnology vary considerably in form, function, and effect. A broad range of forces may exert influences on parties in forming the relationships, including:

- the decline (in real terms) in federal funding for agricultural research;
- changes in intellectual property law;
- the decline in university plant breeding programs;
- federal policies that provide financial incentives for universities to develop commercially valuable property;
- a diminished research capacity by some firms;
- increased regulatory requirements for products and processes that require scientific information;
- the networks of academic and industry scientists that facilitate collaborations;
- state legislative demands that universities do "relevant" work and create jobs; and
- industry needs for cost effective and objective opinions in the product development process.

The potential of these forces to exert influence is clear, yet the specific effects they have on academic research in agricultural biotechnology are not.

Companies generally provide financial and other resources in return for university research, testing, and educational or training services. However, comprehensive data to describe the specific provisions and objectives of various types of UIRs in agricultural biotechnology do not exist. For example, it is unknown what percentage of UIRs focus on (1) basic research, (2) applied research, or (3) product performance testing. Without baseline information, the task of determining how faculty may change their research agendas due to industry relationships, while controlling for other forces that also shape those agendas, for instance changes in public research funding, becomes impossible. Workshop participants confirmed the need for a national database that captures the diversity of the relationships and enables analyses of their effects.

UIRs in all areas grew substantially since 1980. By 1990, 1,056 university-industry research and development (R&D) centers existed, with approximately 60 percent established in the 1980s (Cohen et al. 1998). The share of overall university R&D funding supported by industry, while still small, has steadily increased from 2.6 percent in 1970, to 3.9 percent in 1980, to 6.9 percent in 1990 (Geiger 1992). The most recent data suggest it has risen to approximately 7.7 percent in 2000 (NSF 2000; see Figure 1). Реш Initiative on Food and Biotechnology



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The number of annual patent applications by U.S. universities rose at an exponential rate after the Bayh-Dole Act, from 250 in 1980 to 4,800 in 1998 (Zusman 1999). The number of patents awarded followed a similarly steep trajectory, reaching 3,661 in 1999 (AUTM 2000). According to a survey by the Association of University Technology Managers (2000, p.3), "13,032 Invention Disclosures were reported in fiscal year 2000, up 6% from 12,324 in fiscal year 1999," and "6,375 New U.S. Patent Applications were filed in fiscal year 2000 up 15% from 5,546 in fiscal year 1999." A study of biotechnology companies found that university research generated 4.2 times more patent applications than did other firm research per dollar invested (Blumenthal 1986). The growing role of university technology transfer offices may be one of the reasons for the higher patenting rate involving academic research.

It is important to understand whether these trends among all UIRs are also true among those agreements and relationships in the agricultural biotechnology sector specifically.

GENERAL FORCES SHAPING UNIVERSITY-INDUSTRY RELATIONSHIPS

The U.S. economic crisis of the 1970s focused the attention of policymakers on the lag in American industry between research innovations and product deployment. At the time, there was concern that the U.S. had lost its technological superiority to Japan and some European countries. It was believed that much of the cutting edge science and technology could be found at American universities but that little of that information was getting in the hands of the commercial sector to be turned into world-competitive products. Technology transfer from university labs to firms was considered key to strengthening competitiveness. In response to this perception, Congress passed the Bayh-Dole Act in 1980, which encouraged the commercialization of research by permitting universities to patent and exclusively license discoveries supported wholly or in part by federal research funding. In the same year, the Supreme Court, in the Diamond v. Chakrabarty decision, held that genetically-engineered microorganisms could be patented. The decision, along with subsequent decisions that allowed patenting of genetic materials and plant parts, provided a financial incentive for significant commercial investment in biotechnology. These events were followed in the 1980s by industry cutbacks in research expenditures and a wave of corporate restructuring that further encouraged some firms to pursue university research contracts.

At the same time, public universities diversified their sources of support to compensate for a decline in the rate of growth of federal funding, and to help cover increased costs of research. The real annual growth rate in overall federal R&D funding declined from 16 percent during 1953-1968, to 1 percent between 1969-1983, rebounding slightly to 5 percent between 1984 and 2000 (Hall 2002). For agricultural research, the decline has been more severe. Real public (federal and state) funding for research actually fell from its peak of \$3.54 billion in 1992 to \$3.48 billion in 1999 (USDA-ERS 2001). Public universities also are increasingly evaluated by state legislatures for the economic stimuli they provide. Thus, faculty may face increasing pressure to engage in applied research and industry partnerships thought to foster state economic growth. If true, these forces may mean that the most entrepreneurial scientists will be favored in academic research.

Some state governments perceive that university-industry collaborations will enhance economic development by spinning off new high-technology start-ups and by attracting other R&D companies to high-tech areas around the universities. At least twenty-one states recently have committed or considered research and technology initiatives totaling \$7.7 billion to enhance university research and lure new high-tech investment in all areas, including biotechnology (Business-Higher Education Forum 2001). Although some success stories exist about these university-industry research parks, evidence to support the states' expectations is uneven. For example, researchers Tornquist and Kallsen (1994) did not find that the presence of a research park significantly increased the level of research transfer between universities and private industry.

2.2 Insights from Speakers

Glenn Hicks, Associate Director of Plant Genetics for Exelixis Pharmaceuticals, explained that firms have several options for pursuing a relationship with a university. These include:

- forming a contract for research on a specific clone or method;
- funding a general area of work;
- unrestricted funding of science with the potential for licensing discoveries;
- providing industry services and expertise to the university in joint investigations; and
- a true collaboration in which both parties are involved in research discovery.

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Mark Crowell, Associate Vice Chancellor and Director of the Office of Technology Development at University of North Carolina at Chapel Hill, explained how creation of university intellectual property by the Bayh-Dole Act has spawned approximately 200 U.S. university technology transfer offices and created a strong incentive for university-industry research collaborations. He enumerated six types of agreements that universities and firms can use to form their relationships:

- SPONSORED RESEARCH AGREEMENT defines a collaborative research program between a university and an industry sponsor
- CONFIDENTIAL DISCLOSURE AGREEMENT a party agrees to receive and hold confidential information belonging to the other party
- OPTION AGREEMENT a party acquires the first right to enter into good faith negotiations to acquire a license
- LICENSE AGREEMENT conveys the exclusive or non-exclusive rights to make, have made, use, or sell products or processes covered by intellectual property rights
- MATERIALS TRANSFER AGREEMENT conveys rights to use physical material (usually biological material or compound)
- INTER-INSTITUTIONAL AGREEMENT delineates the rights and obligations of two or more joint owners of intellectual property

Due to the diversity in funding objectives and types of agreements available, each UIR will differ depending on the parties' motivations. For example, Richard S. Cahoon, Vice President of the Cornell Research Foundation, stressed the crucial role of negotiated license terms in determining the public's access to inventions under each UIR. However, knowing a UIR contains a particular set of agreements is insufficient for understanding its potential effects on university research and intellectual property. The specific content of each agreement is key to understanding the influence of a UIR, and therefore important for generating useful baseline data.

2.3 Researchable Issues from Workshop

Workshop participants identified four general questions to guide the collection of baseline information on UIRs in agricultural biotechnology: (1) How many UIRs in agricultural biotechnology exist?; (2) What are the major types of research that are part of UIRs?; (3) What universities participate in which types of UIRs?, and (4) What types of firms collaborate with universities in which types of UIRs? The group also addressed more specific aspects such as distribution of UIRs over universities and firms, the occurrence of basic versus applied research, and university and firm size (see Table 1).

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Table 1 • Key Researchable Issues—Building a Baseline

1. How many UIR's in agriculture biotechnology exist?

- How are the agreements distributed over the public land-grant, public non-land-grant and private universities?
- How are the agreements distributed over different-sized universities?
- How are the agreements distributed over different-sized biotechnology firms?

2. What are the major types of research that are part of UIRs?

- Do the universities conduct basic⁸ or applied⁹ research as part of the agreement?
- Are there differences in the participation of land-grant and non-land-grant public universities and private universities in UIRs?
- How many of the agreements involve product performance testing?
- What fields of agricultural biotechnology are more likely to be involved in UIRs?

3. What universities participate in which type of UIRs?

- What percentage of a university's research budget is from UIRs involving agricultural biotechnology?
- Do scientists from larger universities collaborate more with larger companies?
- Do scientists from smaller universities collaborate more with biotech start-ups firms?

4. What types of firms collaborate with universities in which types of UIRs?

- Does the stage of firm development, e.g., large and mature or small start-up, influence the type of research?
- Do some types of biotechnology firms form agreements that stress product performance testing more than others?
- How many start-up firms owned by university faculty members collaborate with their university?

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⁸ Basic research is generally defined as "... research directed toward increases in knowledge or understanding of the fundamental aspects of phenomena and of observable facts without specific application toward processes or products in mind. For the industry sector, basic research projects are defined as original investigations for the advancement of scientific knowledge which do not have specific commercial objectives, although they may be in fields of present or potential interest to the reporting company" (NSF 1994).

⁹ Applied research is generally defined as "...research directed toward gaining knowledge or understanding necessary for determining the means by which a recognized and specific need may be met. The applied research definition for the industry sector is modified to include research projects which represent investigations directed to discovery of new scientific knowledge and which have specific commercial objectives with respect to either products or processes" (NSF 1994).

Chapter 3 · Effects on Academic Scientists' Research Agendas

3.1 Lessons from Literature

A rich literature on UIRs in other fields may help identify how these relationships could influence university scientists' research agendas in agricultural biotechnology. Surveys have found that researchers with industry support publish at higher rates, patent more frequently, participate in more administrative and professional activities, and earn more than their colleagues without such support (Blumenthal et al. 1986; Blumenthal and Campbell 1996). In addition, some investigators found that university-industry papers are cited more frequently than university-only papers, indicating that university researchers may actually enhance their scientific impact by collaborating with industrial partners (Hicks and Hamilton 1999).

Academic scientists can benefit from industry relationships in several ways. They seek industry funding to support research that might be widely cited and used in applied or technical fields. Widely cited research in turn contributes to the scientist's income and prestige. Industry relationships also provide real-world experience for academic scientists and their students, possibly resulting in the practical use of products developed from their labs. These relationships may also provide financial support and extramural experiences such as internships and future employment opportunities to graduate students. Industry collaborations can lead to peer recognition and consulting opportunities for the collaborating scientists and elevate the university's prestige. Many professors find that corporate research sponsorship imposes a smaller administrative burden than federal grants. Academic scientists may also gain access to matching state and federal grants when they engage in such collaborations.

In addition to the benefits potentially reaped by scientists, surveys of academic scientists also suggest that UIRs pose risks to traditional university values, such as open communication among scholars, the unhampered pursuit of knowledge, and the full and timely disclosure of research findings (Blumenthal 1986). The constant search for patentable products may change the very nature of scholarship and the values of the university, which in turn may change the research agenda of the scientist. Critics also hypothesize that industry collaborations may influence tenure and promotion decisions by favoring scientists who successfully pursue patentable research and thus generate licensing revenues (Business-Higher Education Forum 2001), although empirical evidence of this effect has not been found. Some analysts theorize that the trend toward privatization will lead to under-use of new knowledge and innovations due to the costly transactions of bundling licenses together to gain effective rights to commercialize a product (Foray and Kazancigil 1999). Also, given that firms may not pursue areas of research for which the expected profitability is small, despite the potential for high social net returns, it has been suggested that the influence of UIRs on research agendas could limit such projects. For instance, maintaining a comprehensive public plantbreeding program may be valuable for society, yet it has little direct commercial value.

Academic scientists participating in UIRs may experience "conflicts of commitment" with their teaching, research, advising, and service obligations. One concern is that conflicts of interest may arise when university researchers establish and operate businesses based on

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technology developed by and owned by the university. Conflicts may also arise when scientists' financial interests and their research programs intertwine, thus jeopardizing their ability to critically analyze their research results in an independent and unbiased manner. An example is the debate over whether faculty should be permitted to publish research that is relevant to companies in which they own stock. Although most universities and an increasing number of scientific journals have a policy requiring disclosures of potential conflicts of interest, actions by university administrators and journal editors may be insufficient in content or application to deter or resolve such problems.

Some universities invest in start-up firms based on their faculty members' discoveries or accept equity in companies in lieu of royalties on university-held patents. This practice could tempt universities to influence scientists to tilt their research agenda to help such companies. Such pressures might push the focus of academic research from fundamental to applied research. Evidence of such shifts in research behavior is not clear. While some studies found that involvement with industry is associated with more applied research, others found a relatively stable percentage of basic research from 1981 to 1995, a period during which industry support for academic research and the number of UIRs generally trended upward (Hicks and Hamilton 1999). Consequently, a clear and unidirectional effect by industry relationships on the types of research conducted in fields other than agricultural biotechnology at universities is lacking.

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UIRs may present more subtle risks to the unique cultural components of a university, causing it to become more like that of industry culture. Some analysts describe how conversion of the university into an incubator of economic growth has led to the breakdown of the professional academic class, portraying biologists as outsourced researchers for companies and universities as quasi-for-profit companies (Slaughter and Leslie 1997). They also note the emergence of a new institutional class, as university presidents and industry CEOs come together to strategize how to utilize the current climate to benefit their respective institutions.

Restrictions on information produced as part of UIRs also can be problematic, and academic scientists may alter their research agendas in response. Most universities allow a delay of publication for 60-90 days in order for a company to file for a patent. Critics fear this delay threatens the academic value of openness through prompt publication (Business-Higher Education Forum 2001). Others argue delays of this magnitude are common for journal publication, and thus do not pose a real threat to the freedom to publish (Business-Higher Education Forum 2001). Exploitation of graduate students is another perceived problem. Graduate students involved in industry-sponsored projects typically take six months longer to earn a Ph.D. than those not involved (Business-Higher Education Forum 2001). Also, collaborative research may prevent students from pursuing their own creative research ideas by involving them in specific and predetermined research projects.

The pursuit of increased industry funding by universities may impact the amount of public funds received and the allocation of internal academic resources. State legislatures may feel they can reduce support for public universities that have significant industry funding. However, just the reverse effect may hold. Legislatures that view increased industry funding of academic research as key to economic growth may actually add more to public university research budgets. If there is a perceived positive effect of UIRs on economic growth, universities may face pressure by the legislature to shift internal resources to support industry work. Additionally, the cyclical nature of business profits may make for an uncertain revenue stream to universities thus posing another risk. Notably, public funding, especially by state governments, can also be cyclical as well, adding more uncertainty to university research funding. The financial opportunities from industry funding might also tempt universities to allocate internal resources to attract and manage collaborations such that they insufficiently fund other academic programs. Some commentators express concern that universities are overestimating opportunities for financial gain from UIRs. Thus, they may adopt risky investment strategies, such as using endowments in venture capital investments and investing in start-up firms that support a faculty invention with some commercial value hoping to strike it rich. Legal issues, such as patent infringement, may cause added expense for universities engaged with industry.

3.2 Insights from Speakers

Three academic scientists described their relationships with the agricultural biotechnology industry. Although larger forces also shape UIRs, a recurring message in the workshop was the need to understand the "individuality" of UIRs. This variability poses challenges for framing general issues about the effects of the relationships on scientists' research agendas.

Molly Jahn, a professor at Cornell University, told the workshop that relationships with industry have influenced her research agenda enormously. They have allowed her to create a larger research capacity and achieve more successful outcomes. She described her primary roles as a public vegetable plant breeder and provider of unbiased technical assistance to companies in assessing their products and practices. Despite a strong industry presence in her research, she assures wide public access to her discoveries through innovative licensing arrangements and other methods. She has a strong commitment to delivering public goods via the discovery of new varieties for local crops not provided by major companies and improved delivery of the seeds. For example, she serves local and regional users involved in organic and low input production operations. While cautioning that faculty relationships with industry can cause conflicts and that exclusive relationships pose more risks, she sees tremendous potential for complementary relationships between universities and industry. She has achieved healthy complementary relationships in her program by developing both flexible collaborations and simple, consistent intellectual property relations.

Alan Jones, a professor at the University of North Carolina at Chapel Hill, related both positive and negative experiences with industry research partners. He articulated the two driving motivations that ultimately shape the relationships - companies want to make money and academic scientists want to publish papers. He explained that in any successful UIR, both sides must contribute intellectually, but will likely do so in different ways. Industry can do "big science," but it often costs them in creativity. Academic labs are creative but cannot afford the "big science" platforms often owned by industry. Thus, he asserted, the elements of a successful collaboration emerge: academics need access to the "big science" platforms and industry needs access to the academics' ideas. He described a Collaborative Funding Awards program that facilitates such collaborations in North Carolina. In this program, company scientists are co-principal investigators and all stakeholders (company, university, state, and non-profit) may contribute a financial stake to share the risks and rewards. Such complex collaborations require a well thought out research agreement. He emphasized that universities should own the intellectual property. He also argued that collaborations must be facilitated by a third party that speaks both university and industry languages, subsidizes and monitors the collaboration, and looks after other details. The non-profit North Carolina Biotechnology Center plays this role in his positive industry collaboration. In Jones's negative experience, he initiated the ideas, but the firm modified it and then reorganized and did not deliver the promised resources to complete the agreement.

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Harry Klee, a professor at the University of Florida, has an intimate knowledge of working with industry. As a scientist with Monsanto for eight years, some of his responsibilities involved directing collaborations with academics and licensing academic research discoveries. He now receives industry funding for approximately 20 percent of his university research projects that involve specific, contracted goal-oriented research and joint university-industry sponsorship. For some projects, industry sponsors hold the first right of refusal to license the discovery. Klee stated that he was motivated to seek industry collaborations for several reasons, including: a desire to see his research have a positive impact on society; to gain access to cutting-edge technology not available otherwise; to participate in cross-disciplinary science, and to find support for applied horticultural research on low value crops not available in the public sector. Note that this last motivation directly contrasts with the hypothesis that industry support may lead to the neglect of such research on 'minor' crops. However, he perceives a fundamental conflict between the roles of universities, to educate and disseminate knowledge, and industry's goal, to earn money. For example, conflicts can also arise when faculty members start thinking about start-up companies, including secrecy, rights of students and postdoctoral researchers, and funneling of results to the new entity. Universities must be diligent in enforcing rules that cover such issues. Klee believes that partnerships with industry have had a positive impact on his program, and are usually researcher-driven. In his view, the major issues are specific to the roles and responsibilities of the university, not industry.

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Social scientists in the midst of two studies of UIRs in agricultural biotechnology reported preliminary findings of their investigations. Lawrence Busch, a Professor at Michigan State University, was commissioned by the Faculty Senate of the University of California at Berkeley to conduct an evaluation of the agreement between UC Berkeley and Novartis. Key areas of concern for the Faculty Senate included the amount, direction, and type of research conducted by faculty, students, and postdoctoral researchers, and the impact of the agreement on the flow of scientific knowledge in the university. Professor Busch described how the Berkeley-Novartis agreement reflected the evolution over time of three models of the university:

1. UPLIFTING THE MASSES

- Research is conducted for societal or public good, free circulation of knowledge exists, and knowledge is extended to "agricultural and industrial classes."
- Education is for citizenship in democratic society, ethical behavior, and leadership.

2. CREATORS OF KNOWLEDGE

- Research is pursued for knowledge's sake, and there is free circulation of knowledge.
- Education is for learning the facts about the world and "covering the material."

3. ENGINES FOR GROWTH

- Research is conducted to incubate new business, to discover a cornucopia of new technologies, and to help create entrepreneurs.
- Education is primarily oriented to "vocationalism."

Busch stressed there were no villains in the Berkeley-Novartis relationship, but the agreement raises fundamental questions about the role of the university in society and the direction of academic research. The risks that these forces pose are likely greater for universities and scientists with fewer research resources and less bargaining power with industry partners than universities such as the University of California at Berkeley. William Lacy, Associate Provost at the University of California at Davis, described the preliminary results of in-depth interviews with administrators and scientists from university and industry partners engaged in research collaborations.¹⁰ A revealing finding is that academic administrators and scientists expressed a preference for different criteria than industry scientists in their selection of research problems. Not surprisingly, the university informants favored more publicly oriented objectives, while the industry scientists placed more emphasis on customer needs, marketability, and patents and licenses. This difference in research agendas implies that both parties must clearly specify their objectives in the formation of a UIR to assure compatibility. Another key finding is that administrators who help to form UIRs and the university scientists who participate in them tend to define the public good as research that leads to the creation of commercialized products. This suggests a narrowing of the traditional definition of the public good toward private goods. These scientists and administrators also tend to emphasize how collaborations with industries introduce them to relevant or "real world" problems. This finding begs two linked questions: (1) to what degree are UIRs replacing the Cooperative Extension Service's (CES) role in connecting land-grant universities to the "real world"? and (2) what is the effect on public goods delivery in agriculture?

3.3 Researchable Issues from Workshop

Workshop participants identified two areas of investigation into the effects of UIRs on scientists' research agendas: (1) influences on the research topics and direction of academic scientists, and (2) effects of industry funding on academic culture and scientists. For the first topic, participants addressed the major factors that influence scientists as they set research agendas and the effects of university tenure and reward systems, technology transfer offices, and start-up opportunities on research topic and direction (see Table 2). With regard to funding mechanisms, participants questioned: whether academic scientists' have allowed industry funding to change the focus or direction of their work or publications; what constitutes a well-balanced private and public funding portfolio; the perception of public good; the effect different funding sources have on the types of scientific outputs, and whether there is an association between funding sources and basic versus applied research (see Table 2).

10 The interviews are from the first phase of the USDA project that co-sponsored the workshop.

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Table 2 - Hey Researchable Issues—Effects on Scientists' Research Agendas

Influences on research topic and direction

- 1. What are the major factors that influence academic scientists as they set research agendas?
 - Do academic scientists who collaborate with industry do more applied than basic research than their peers who do not have industry support?
 - How does access to proprietary information and technologies from industry affect a scientist's choice of research topics?
 - Does industry funding exert more leverage on scientists' research agendas than federal government or other funding?
- 2. Does the university tenure and reward system affect a scientist's incentive to form industry relationships and their choice of research topics?
 - Does the scientist's rank (assistant, associate or full professor) influence the research direction or choice of funding?
 - Is there an institutional mechanism, such as criteria for attaining tenure, that encourages scientists to pursue certain forms of research funding?
 - Do incentives exist to research areas that are not funded by the private sector?
 - In terms of university press, is private or public finding more relevant to a scientist's career success?
- 3. Does the existence of an Office of Technology Transfer (OTT) affect an academic scientist's research agenda?
- 4. To what extent does the opportunity to participate in a start-up company influence an academic scientist's research agenda?

Effects of industry funding

- 1. Have academic scientists allowed their work plan/research objectives/publications to be changed by industry funding?
- 2. Does industry funding have a larger effect on scientists' research than federal funding?
 - Does demand from industry for certain types of research enhance or distort the scientist's research agenda?
- 3. Do academic scientists with private funding and public funding have similar definitions of the public good?
- 4. What is the "correct" balance between publicly funded versus privately funded research?
- 5. Does collaboration with industry affect the types of scientific outputs, e.g., the types of traits of genetically engineered crops?
- 6. Has basic research shifted to private sector? How much basic research is patentable?

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Chapter 4 · Intellectual Property and Technology Transfer

4.1 Lessons from Literature

Intellectual property (IP) and technology transfer (TT) are some of the biggest concerns in university-industry research collaborations. The Diamond v. Chakrabarty decision and the Bayh-Dole Act changed the possibilities and incentives for universities to retain title to inventions funded wholly or in part by federal research funds. These decisions and policies have fundamentally transformed the academic biological science landscape over the last twenty years.

Findings from studies of academic IP and UIRs in other sectors include:

- Firms whose scientists collaborate with top university scientists tend to earn more patents and more highly cited patents than do other firms (Zucker et al. 2002).
- Patented discoveries from UIRs may provide licensing revenue to support other university activities.
- Most universities retain title to the patented inventions, but split the licensing income with the faculty inventors.
- Annual licensing revenue has grown from \$160 million in 1991 to \$862 million in 1999 (Poyago-Theotoky et al. 2002).
- Still, licensing revenue is a very small percentage of total university support; it was only 2.7 percent in 1998 (Business-Higher Education Forum 2001).
- Only a slim number of university patents are licensed and even fewer generate significant revenue.

Whether these findings can be applied to UIRs in agricultural biotechnology and the related university IP has yet to be determined.

Despite the revolution in university based IP, fewer than half of the universities with TT offices realize enough royalty income to cover the administrative costs associated with them. Success often depends on a small number of "blockbuster" patents or copyrights, the size of the technology-transfer office, and serendipity. Most universities spend more money obtaining patents than they receive in royalties from licensing them (Business-Higher Education Forum 2001).

Although universities and public funds support agricultural biotechnology research, many patents remain in private hands. Debby Delmer of the Rockefeller Foundation noted that a recent survey carried out at the University of California (Graff et al. 2003b) showed that public sector institutions in total hold more patents on agricultural biotechnology discoveries than any single private company. However, private companies were granted approximately seven times the number of "crop agriculture" patents than universities and governments in 2000 (Graff et al. 2003a; see Figure 2). Furthermore, the private sector holds three fourths of

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all plant patents, including those generated by publicly funded research (Bennett and Graff 2002; Conway 2003). Moreover, the private sector controls the rights for the use of the two most common plant transformation techniques, via the use of Agrobacterium or the gene gun. This means that every plant transformation at a university destined for commercial purposes requires a material transfer agreement with one of the two companies that controls those technologies. The gene gun was developed by a public university (Cornell) and then sold to the private sector, a case of what some may term converting a potentially public good into a private good.

Figure 2 Growth in the Number of U.S. Patents over the Biotechnology and Genetics of Crop Agriculture, 1985-2000



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4.2 Insights from Speakers

Mark Crowell of the University of North Carolina at Chapel Hill emphasized that the IP and TT from UIRs can be important forces in stimulating new economic development. He also noted several issues for universities entering such agreements, including:

- the need to balance IP and TT with the tradition of openness at a university;
- designating "inventorship" versus authorship;
- freedom to publish following a reasonable delay;
- sharing of research materials, patenting, marketing and use of genetic material;

- conflicts of interest for the faculty entrepreneurs;
- insider trading concerns, and
- institutional conflicts of interest.

Richard Cahoon, Vice President at Cornell Research Foundation, explained that Cornell attempts to use the basic principles of academic freedom as guidelines for technology transfer. However, when those principles meet practical realities, balancing the public good versus practical concerns requires license structures that accommodate both parties. He explained that the negotiation of the UIR and licensing agreement terms determine that balance, and described which terms are and are not negotiable at Cornell.

Research Collaborations	Non-Negotiable	Negotiable
Secret research	х	
Publication timing		x
Research direction	?	Х
Scope of work	?	X
Indemnify university	Х	
Intellectual property ownership	Х	
Commercial rights		Х

The question marks for research direction and scope of work reflect uncertainty over how those terms are decided in practice.

Licensing Agreements	Non-Negotiable	Negotiable
IP ownership	х	
Indemnify university	Х	
Use of names	Х	
Due diligence	Х	
Scope of rights		Х
Fees & Royalties		Х
Fees & Royalties		х

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Clearly, the domain for negotiation centers on the scope of rights enjoyed by the firm and the fees and royalties paid to Cornell University. Finding the appropriate balance in the licensing structure involves a tension between rights and fees and royalties versus the university's primary mission of education and research. An exclusive license usually requires significant up-front fees, effective royalties with appropriate minimums, covering patent costs, and diligence milestones. With a non-exclusive license, "sliding scales" of terms are used by Cornell depending upon the degree of exclusion granted to the licensee, thus enlarging the range of negotiation.

Debby Delmer described two IP initiatives that the Rockefeller Foundation is pursuing to facilitate the use of agricultural biotechnology by developing countries to address their food and resource needs. She explained that the logic for universities and foundations to collaborate on the initiatives is to find ways to simplify the congested IP landscape for public sector R&D, especially for specialty crops and for research for humanitarian purposes. The first initiative, called the Public Sector Intellectual Resource for Agriculture (PIPRA; see www.PIPRA.org and Atkinson et al. 2003), is designed to develop a strategy for the collective management of agricultural biotechnology IP among key public-sector institutions. Ultimately, the program would promote good relations with the private sector and engage in revenue-generating licensing of technologies. However it would also need to avoid, as much as possible, past policies that licensed technologies exclusively to the private sector and would make every effort to keep IP available for the development of subsistence and specialty crops. For example, under the strategy to develop this program, a publicly available database of tools and technologies would make known which tools and technologies in the public domain were never patented, which patents on tools and technologies are currently held by the public sector, and provide information on how to access these tools and technologies.

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The second initiative was created by the African Agricultural Technology Foundation (AATF; see www.aftechfound.org), an African-owned and led organization based in Nairobi, Kenya. The AATF seeks to have companies provide their IP royalty free to countries in sub-Saharan Africa. Delmer pointed out that some combination of four reasons may persuade a company to do so: (1) such actions may improve global public acceptance of biotechnology; (2) the African market share is currently minor; (3) donations can help establish future markets in Africa, and (4) the companies may have a real concern for hungry people. However, companies need certain assurances to move forward, such as good stewardship, limited liability exposure, protection of their bottom-line, and knowledge that the product will reach the resource poor farmer. The AATF helps meet these needs. It stewards projects that require private sector technologies and address real needs of African farmers. It also negotiates licenses for such projects, controls the sublicensing to the groups undertaking the project, and stewards the project from inception to completion.

Delmer suggested that these types of cooperation between the public and private sector could serve as a model for future efforts. She left the audience with a guiding question: "Is there a way the large private companies might join with the public sector and small private sector companies to help move biotechnology applications forward in the developing world as well for the development of new horticultural and specialty crops?" Until now, companies have been unlikely to invest the required money to develop such minor crops because the small market will not generate sufficient revenues to recoup the costs. However, they may, in the future, be willing to let the public sector use their tools to develop products for such crops.

Hope Shand, Research Director of the non-profit ETC Group, was not as sanguine about resolving IP issues involving agricultural biotechnology. She noted that with the advent of

genetic engineering and the evolution of IP laws, a small number of firms have won farreaching claims of ownership over biological products and processes. The power of utility patents gives the companies the legal right to exclusive access to those technologies for 20 years.¹¹ ETC Group is concerned that the creation and control of IP in agricultural biotechnology is stifling the free flow of knowledge and genetic resources within the public research community. The group is also concerned about the appropriation of the products of public research for private profit, citing the recent action to commercialize "golden rice" (a genetically modified rice enhanced with to produce Vitamin A) after a decade of publicly funded research. Shand emphasized the critical IP issues requiring attention to meet the needs of poor and developing countries. In her view, the current IP regime stifles innovation and hinders competition in agricultural biotechnology, yet the U.S. government proposes this system as a model for the rest of the world.

Harry Klee feels that most UIR issues and concerns emanate from the academic side. For instance, many universities put considerable effort into patents and licensing and view patents as cash cows in a time of tightening budgets, which encourage faculty entrepreneurial efforts. Patenting is necessary to see a real societal impact because companies will not pursue discoveries without patent protection. However, patenting is a time-consuming process, if done right. Therefore, the patenting process imposes an opportunity cost by using the scientist's time on an activity other than research.

4.3 Researchable Issues from Workshop

Workshop participants focused primarily on issues of barriers and delays to the free exchange of knowledge and information caused by IP regimes. Specifically, they felt more research is needed on the causes and effects of UIRs on the free exchange of academic knowledge and information and delays in dissemination, discovery, and innovation (see Table 3). Developing metrics for measuring the barriers and delays would be an important part of that research task.

The efficacy of the TT process at various universities raised many questions. This area of research involves questions about revenues generated by different types of TT offices, an assessment of the performances of TT offices at different universities, including patenting and licensing activities, appropriate financial returns to different parties involved, and the level of resources devoted to IP (see Table 4).

Another common issue involved IP and licensing arrangements. Key questions surrounding the IP and licensing issues include the types of licensing arrangements and their effects, ways to effectively pool intellectual property rights, the influence of university's funding portfolio on the licensing practices, the faculty's view on patenting, the relationship between patenting and publication, analysis of patents, and the cost and benefit analysis of patenting (see Table 5).

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¹¹ According to U.S. patent law, the term of the patent shall be generally 20 years from the date on which the application for the patent was filed in the United States or, if the application contains a specific reference to an earlier filed application under 35 U.S.C. 120, 121 or 365(c), from the date of the earliest such application was filed, and subject to the payment of maintenance fees as provided by law.

Table 3 - Hey Researchable Issues—Intellectual Property and Technology Transfer

Decrease in free exchange, barriers, and delays

- 1. How often are university scientists denied access to research materials or information?
- 2. Is there a decrease in the free exchange of knowledge and information, and, if so, what force(s) are driving it?
- 3. Are publication delays due to intellectual property issues prevalent?
 - How should the delays in discovery and innovation from intellectual property issues be measured?
- 4. How many crops (transgenic and otherwise) have been developed but have not been used?
 - What are the barriers to commercialization?
 - Do universities support defensive or blocking patents? How do UIRs affect communication among colleagues in the scientific community?
- 5. What has been the trend since Bayh-Dole in terms of number of material transfer agreements?
- 6. Do universities allow material transfer agreements with reach-through privileges?
- 7. What are the costs to ∏ personnel to university scientists (including their time) in negotiating intellectual property and technology transfer arrangements?
 - How can these costs be reduced?

Table 4 - Hey Researchable Issues—Intellectual Property and Technology Transfer

Office of technology transfer and performance measures

- 1. What are the costs and revenues of university technology transfer operations and IP transactions?
- 2. Where does the money come from to finance the search for IP in universities?
- 3. What is the range of resources that different universities dedicate to IP?
- 4. What drives patenting licensing at universities? Who is doing the marketing of university patents?
- 5. What are the performance measures for offices of technology transfer?
- 6. What are the appropriate financial returns to offices of technology transfer, faculty, the private sector, or public interest?

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Table 5 - Key Researchable Issues—Intellectual Property and Technology Transfer

Intellectual property/licensing

- 1. What sectors of society are helped by various types of IP created in industry and universities?
 - What are the deficiencies in our society that agricultural biotechnology might be used to address?
 - What is being done for the public good? What tools or products have had environmental benefits or fostered economic development?
- 2. What sort of patents are being generated at universities?
 - How many patents are for products?
 - How many patents are for processes?
 - What is the view of faculty on patenting?
 - What are the costs and benefits of patenting?

3. Does a university's funding portfolio affect its patent licensing practices?

- Is the proportion of a university's patents falling under various technology domains affected?
- Are higher levels of industry funding associated with more exclusive licensing of university intellectual property?
- 4. Are university licenses put to the best possible (highest) uses?
 - Do exclusive licenses have "teeth" or milestones built into them to ensure that revenues are collected or technology is used and not shelved?
 - What are the global impacts of licensing agreements?
 - When universities are granting exclusive licenses, do they include humanitarian exclusions?
- 5. Is intellectual property pooling feasible?
- 6. Have scientists chosen not to license technologies from industry?

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Chapter 5 · Industry and Critical Views of University Industry Relationships

5.1 Lessons from Literature

Empirical analyses suggest that university research enhances the power of a biotechnology firm's research rather than offering a substitute for it (Hall et al. 2000). University collaborations enable firms to gain access to university resources unavailable or too expensive for the firm's laboratories, such as "star" scientists and unique biological materials. Faculty consultancies and graduate student employment also may provide access to valuable university expertise. Some collaborations give firms the option to obtain early access and the right of first refusal to potential technological innovations through exclusive licensing arrangements when the true potential is uncertain but perhaps large. Firms seek to transform such university discoveries into commercial products and create flexible mechanisms to explore a wide range of commercial interests while leveraging their risks. Even if a discovery has no immediate use, the synergy from working with university researchers may enhance a firm's competency or prestige and lead to new business opportunities.

In addition to the potential benefits, industry collaborators may perceive risks from their research relationships with universities. For instance, academic researchers may not deliver products in timely fashion. Companies have to expend time and effort with university collaborators to assure their project moves toward projected goals. Firms may be concerned that proprietary corporate information shared with a university scientist might leak out to the public or to competitors. Firms also may worry about less formal disclosures of their proprietary information, such as discussions among faculty members. Some companies may not believe that university scientists have insights that will lead to commercial products, or that the costs and challenges of working together are too high. Industry may also be concerned about imbalance between the high incidence of patenting basic research and the relatively limited potential for developing those discoveries into marketable products. More carefully directed public funding and astute licensing may be necessary to make more effective transitions from university research to industrial development.

5.2 Insights from Speakers

Glenn Hicks, Associate Director of Plant Genetics for Exelixis Pharmaceuticals, presented an industry perspective on UIRs in agricultural biotechnology by stressing that: "Not all companies are the same!" He suggested that to understand a firm's involvement in UIRs, researchers should consider its size, stage of development, culture, motivations, and funding mechanisms for university agreements.

For example, well-established firms tend to be:

 more product focused and have a strong business model and clear path to the marketplace with high motivation to pursue profits, and

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• more likely to target substantial funding to key enabling technologies and may even acquire or develop technologies defensively to block competitors.

In contrast, non-public, start-up companies tend to be:

- less focused on immediate products, more science and technology focused, and more receptive to taking risk;
- less constrained in the ways university research may be structured and funded, and
- motivated to establish scientific credibility and progress in their research in a cost-effective manner.

A basic inference from Dr. Hicks' remarks is that the type of industry funding is influenced by the stage of a company's development. Universities may find they have a mission more consistent with start-ups because of their strong science and technology focus. Industry partners face key issues with UIRs, including: the lack of continuity of relationships due to the short-term of business cycles versus research time frames; keeping university scientists "on track," and the free exchange of information and reagents. Hicks identified four elements of a successful UIR:

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- 1. scientists are primary contacts that establish the relationship;
- 2. flexibility exists for industry and the university;
- 3. trust among scientists is crucial; and
- 4. researchers need to understand but not focus on legal and IP issues.

John Anderson of Monsanto, a former university professor, said relationships with academic researchers were key to Monsanto's development and commercialization processes. Monsanto has basic research agreements with more than 70 universities and other institutions and with 75 universities and other institutions for regulatory science. Each relationship usually involves a network of scientists on the campus. Monsanto's university relationships are so important that their field researchers are accountable for them. Monsanto expects universities to:

- proactively educate policy makers on the benefits and importance of agricultural biotechnology;
- provide leadership necessary to successfully introduce and steward new technologies into the marketplace, and
- continue to advance the frontiers of science with new discoveries and innovations that benefit growers, consumers, and trade organizations.

Because academics generally do not understand the commercialization process, how contracts are negotiated, and the concept of risky investment, Monsanto has created the Innovation Management in Agribusiness Program with the Kenan-Flagler Business School at the University of North Carolina. Anderson closed by saying that positive UIRs accelerate the development of new ideas, but the long time frames and limited resources involved often limit such progress.

Sheldon Krimsky, a professor at Tufts University, began his critique by posing the question: "Where can we get disinterested science?" Not just a recent concern, the scholarly commentary about the intrusion of business influence into university science has been ongoing throughout the last century. He pointed out three areas of concern besides the potential increase in university reliance on industry funding. First, universities are equity partners in professor-initiated companies, creating a complex set of institutional and faculty conflicts of interest. For example, one study found that 15 percent of faculty held equity in 10 or more start-up companies supporting research at the same institution (AUTM 2000). Second, trade secrecy has become more prevalent in universities – surveys indicate that between 12 to 34 percent of academic researchers have been denied access to their research results to uphold trade secrets (Bekelman et al. 2003). A third concern involves the ethics associated with scientific publications by researchers with vested interest in study outcomes. In a study by Krimsky and colleagues (1996), 34 percent of the articles in 14 high profile journals were authored by scientists with a financial interest in the outcome of their respective studies. The above findings pertain primarily to biomedical research, and may or may not apply to UIRs in agricultural biotechnology. However, research on the effects of industry funding on medical research may serve as a warning of the potential risks to impartial university science for agricultural biotechnology. For example, Krimsky noted that several investigations have found bias toward the industry sponsor's drugs, bias in the selection of journal articles published, and academic research that favors corporate views of risk (Davidson 1986; Rochon et al. 1994; Kjaergard and Als-Nielsen 2002).

Hope Shand said the ETC Group and many other civil society organizations find UIRs in agricultural biotechnology to be problematic. The idea of such collaborations is not the problem, but rather the enormous disparity in the relative power and position of the partners. The increasing consolidation in the plant breeding and seed industry has given the surviving firms considerably more bargaining power in relationships with universities. She asserted that commercial plant breeding and agricultural biotechnology are now proprietary sciences and virtually all knowledge associated with them is private. She explained that these conditions might not be so worrisome if public sector agricultural research support was thriving, but it's not. Further, she explained that excessive control of key genetic resource information may be most problematic for developing countries because large corporations are most interested in industrial crops with markets large enough to cover the investments necessary to develop and commercialize new biotechnology varieties. For instance, corporate R&D focuses on creating products that require farmers' to purchase off-farm inputs, instead of varieties needed in developing countries, such as those with durable disease resistance and improved nutritional characteristics. She posed the fundamental question: "With the decline of public sector research, who will address the needs of poor farmers?" ETC and other like-minded organizations are concerned that the private sector research agenda is influencing public sector research such that these needs are not being met. She noted that Molly Jahn's exemplary efforts to produce improved crops for local and regional markets, cited in chapter 3, are very rare.

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Chapter 6 · Interpreting the Larger Workshop Messages

To interpret the messages from the workshop, Bob Goodman, a professor at the University of Wisconsin, drew on his experiences with university collaborators when in industry, and industry and government partnerships since his move to academe. In his research program, he usually receives short term and small amounts of funds through UIRs. He considers them some of the most flexible and "risk-enabling" sources of funding. He stated that industry funding has supported the most productive graduate student he has encountered in his academic career. However, Goodman's only large contract with industry did become problematic in subsequent IP tie-ups and hindrance of subsequent research efforts. Like other bioscientists speaking at the workshop, Goodman considers UIRs an important component of his approach to student education.

Goodman went on to note that the long academic history in the U.S., beginning with the land grant mission, evolved through the post-WWII government funding of science in which university-government relations were prominent. Then, in 1980, the Bayh-Dole Act introduced UIRs to play a "preemptive" public good role. He explained that the Act's original purpose was not necessarily to make universities the "handmaidens" of industry, yet it is true that seminal agricultural biotechnology inventions were licensed exclusively to individual private sector (and multinational) companies in the early to mid 1980s. He rhetorically asked: "Was this the proper fulfillment of the public good envisioned?"

Goodman recommended a continuing discussion of the following UIR issues:

- Rethink and redefine the range of public goods and the role of universities in their promotion and their stewardship;
- Rethink the structure and breadth and terms of licenses and material transfer agreements;
- Re-scope the importance of economic development as a public good;
- Refine and reaffirm the proper roles of universities;
- Rethink the proper balance of public support for universities;
- Reconsider the value of solidarity and common cause among the public universities in dealing with industry, and
- Reaffirm the underlying values of our public institutions in agriculture.

He further recommended that a coalition of institutions should establish a perpetual forum for public engagement on the topic of UIRs in agricultural biotechnology.

While the workshop and the literature often break apart UIRs to analyze the separate forces and effects, Goodman believes the relationships have many of the properties typical of a complex system. He reminded participants that success in understanding the challenge of planning within, and problem solving for, a system characterized by complexity demands a different approach than in simpler or more linear systems. He asked the group to consider an

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analogy with the civilian airline industry – airplane manufacturing, airports and their governance, flight control systems, meteorology, human operators, telecommunications, etc. To ensure safety and smooth operations, society needs guiding principles for such a complex system. The first is robust protocols. Another is system redundancy. The system also requires a focus on planning, risk reduction, and the ability to respond effectively to the unexpected and unplanned failure of a component. All of the above apply to UIRs. Goodman noted that the complex systems view requires an approach that is robust, resilient, and responsive to unplanned or unanticipated failures. This approach is much more desirable than a highly analytical or solely predictive approach where individual failures or issues are anticipated and remedies for each are designed. In closing, he cited Yale history professor Daniel J. Kevles, on the need for a broader perspective in the public debate about the politics of science in public institutions and for the public good:

"What we really need is public debate among the experts about vexing issues such as genetically modified foods (do they need to be regulated?), the patenting of human genes (does the practice serve the public interest?), and the commercial dimension of academic research (how corrupting is it?). Given its conflicts of interest, the American scientific enterprise merits greater scrutiny by the press and the political system. Now that science and technology pervade so much of our lives, it would surely improve the nation to have a scientific leadership with the publicinterest engagements of (Vannevar) Bush, (James B.) Conant, and (Robert) Oppenheimer, but one that is also emancipated from their generation's habit of secretive elitism and aware that the public interest may not best be served by this generation's wild enthusiasm for business (Kevles 2002)."

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Chapter 7 · Conclusions

The authors drew three overarching conclusions from the workshop. First, our scientific knowledge (from peer reviewed studies) about UIRs in agricultural biotechnology is scant. Baseline information on the nature of these UIRs and how they function is deficient. As a consequence, we are largely without basic intelligence on the overall nature and evolution of the relationships, one of the most important revolutions in our agricultural research system. Second, what little is known about UIRs in agricultural biotechnology, suggest the framework for these relationships varies from case to case. They often depend on the particular motivations and personal relationships of scientists. While the scientist's desire to publish papers (thereby enhancing her professional stature and salary potential), and the firm's desire to make a profit may be common motives for developing UIRs, the "individuality" of UIRs makes it difficult to generalize about their causes and effects. Although the diversity of the relationships may lead to more innovation in general, it also may introduce risks for certain universities, firms, and agricultural sectors. Without specific data and research on the varied UIRs, the identification of current or impending problems and potential policy actions to remedy the problems is largely guesswork. Third, mirroring the diversity in the relationships, the effects of the UIRs on technology innovation and subsequent social, economic, and environmental change will be varied as well. Because UIRs are embedded in larger university, industry, and government institutional and policy settings, their performance should be examined within this larger complex system.

Academic research has played a crucial role in building knowledge, technology, and capital for U.S. economic and social development. Traditionally, new knowledge discovered in academe and financed mostly by federal and state governments found its way into industry largely through public disclosure, to create new products and services that benefited private firms, consumers, and society in general. Industry was involved in varied ways in this research process from identifying problems to developing commercial applications of innovative technologies. The development of U.S. agriculture through the mid-1980s typified this traditional university-government-industry collaboration. The relationships were part of the "Uplifting the Masses" and "Creators of Knowledge" eras for U.S. universities, as described by Professor Lawrence Busch.

The historic pattern of university, industry, and government R&D relationships in agriculture has changed, perhaps with profound implications for the future of science and social development. Accentuated by a historic Supreme Court decision (Diamond v. Chakrabarty, 1980) and new federal legislation (the 1980 Bayh-Dole Act), universities and industry have strengthened their dominant roles in scientific discovery and technological innovation. We are now experiencing the "Engines of Growth" phase that Busch describes, with new potential benefits, costs, and risks. As noted above, this transformation has occurred without good data and science on the forces and the likely long-term effects on the social, economic, and environmental performance of our agricultural system.

These issues deserve more investigation. For example, the links between academic research and the timing of industrial innovation calls for greater exploration. A recent survey suggests there may have been a serial decline in the average time lag between academic research and the first related commercial introduction (Mansfield 1998). If society is obtaining bene-

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fits from the commercialization of an academic discovery more quickly than a decade ago, it may be important to promote closer working relationships between firms and academic researchers. Arguing against this, Mansfield claimed that the decreased average time lag implies that universities are simply conducting more applied and short-term work. In that case, the declining lag would not necessarily infer that fundamental knowledge is being translated more quickly into commercial products and processes. The social, economic, and environmental effects of a shorter research-innovation linkage for agricultural biotechnology have not been investigated.

Despite the increased role of industry in academic research, the U.S. industrial base still relies heavily on public science, that is, on knowledge originating from universities, research institutions, and government laboratories. The biotechnology industry is especially dependent on public science. By tracing the rapidly growing citation linkage between U.S. patents and scientific research papers, researchers Narin and colleagues (1997) find that 73 percent of the papers cited in U.S. industry patents are public science, authored at academic, governmental, and other public institutions. Industrial scientists authored only 27 percent. However, this finding may reflect that industry scientists are often discouraged from publishing findings. Thus, the number of publications by industry scientists cited in patents may not indicate the agricultural biotechnology industry's actual degree of dependence upon public research.

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At the close of the workshop, participants voiced strong sentiments about the crucial role of public research by government and academic scientists to complement industry forces in technology development. They were particularly keen that government act as the essential third party in UIRs. Basic questions about public sector roles reflect those concerns. With increasing privatization of the plant breeding industry, is public sector plant breeding sustainable? Is the public sector maintaining enough public good research? How has the size and orientation of government funding changed? Are sufficient numbers of young scientists being trained? How have UIRs influenced these changes? How have these changes affected faculty research agendas?

University-industry relationships are increasing, varied, and promise to be a fixture in U.S. science and technology development for the foreseeable future. The theoretical and empirical literature on such alliances provides general insights about why the relationships form and their effects, albeit with mixed evidence on some key points. Research has not investigated the UIRs in agricultural biotechnology in sufficient detail to understand the various motivations at work and the effects on the research process and outcomes. New theory and data are needed to examine the connections between basic and applied research and between public and private R&D in this area of agricultural innovation. Sociological and economic contributions informed by contemporary bioscience behaviors are needed to formulate cogent models that capture all salient factors.

Little quantitative work has yet emerged on UIRs in agricultural biotechnology. In particular, few empirical analyses have examined university-industry research relationships, and models that do exist have specialized in only specific aspects of the innovation and transfer system. One of the primary objectives of the USDA project that co-sponsored the workshop is to contribute such empirical analyses. In doing so, it will be important to seek specific information on project size, scope, objectives, clarity of purpose, basicness, publicness, and risk of failure. The project aims principally to identify how UIRs affect the public good aspects of university research, the breadth of scientific research, and the types of plant or animal characteristics that are likely to be forthcoming from them. With the knowledge of such key relationships, the attributes of UIRs most likely to foster desired university and industry benefits can be

identified for public and private decision makers. The sponsors hope that the workshop findings, by framing salient researchable questions, will help focus scarce research resources on seeking answers that will help universities, industry, and government better manage UIRs to achieve desirable public policy goals. The improved understanding may also help address some of the broader concerns being raised about the adoption of agricultural biotechnology.

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References

- Association of University Technology Managers (AUTM). 2000. *AUTM Licensing Survey: FY* 1999. Northbrook, IL: The Association of University Technology Managers, Inc.
- Atkinson, R.C. et al. 2003. A Collective Strategy for Managing Intellectual Property in Agricultural Biotechnology. *Science: in press.*
- Bekelman, J.E., Y. Li, and C.P. Gross. 2003. Scope and Impact of Financial Conflicts of Interest in Biomedical Research. *Journal of the American Medical Association* 289: 454-465.
- Bennett, A.B. and G. Graff. 2002. *Intellectual Property in Agricultural Biotechnology: Fueling the Fire or Smothering the Flame*. Berkeley, CA: Office of Research Administration & Technology Transfer, University of California.
- Blumenthal, D. 1986. University-Industry Research Relationships in Biotechnology: Implications for the University. *Science* 232 (4756): 1361-1366.
- Blumenthal, D. and E.G. Campbell. 1996. Participation of Life-Science Faculty in Research Relationships with Industry. *New England Journal of Medicine* 335 (23): 1734.
- Blumenthal, D., M. Gluck, K.S. Louis, and D. Wise. 1986. Industrial Support of University Research in Biotechnology. *Science* 231 (4735): 242-246.
- Business-Higher Education Forum. 2001. *Working Together, Creating Knowledge: The University-Industry Research Collaboration Initiative*. Washington, D.C. Available at: www.acenet.edu/bookstore/pdf/working-together.pdf.
- Cohen, W.M., R. Florida, L. Randazzese, and J. Walsh. 1998. Industry and the Academy: Uneasy Partners in the Cause of Technological Advance. In *Challenges to Research Universities,* Roger G. Noll, ed., 171-199. Washington, D.C.: Brookings Institution.
- Conway, G. 2003. "From the Green Revolution to the Biotechnology Revolution: Food for Poor People in the 21st Century." Paper presented at a Directors' Forum at the Woodrow Wilson International Center for Scholars, Washington, D.C., March 12, 2003, 16.
- Davidson, R.A. 1986. Source of Funding and Outcome of Clinical Trials. *Journal of General Internal Medicine* 1 (May-June): 155-158.
- Foray, D. and A. Kazancigil. 1999. "Science, Economics and Democracy: Selected Issues." Paper presented at the World Conference on Science, UNESCO-ICSU. Budapest, Hungary: June 26 - July 1, 1999. Available at: unesdoc.unesco.org/images/0011/001163/116331eo.pdf.
- Geiger, R.L. 1992. The Ambiguous Link: Private Industry and University Research. In *The Economics of American Higher Education*, W.E. Becker and D.R. Lewis, eds., 265-297. Boston: Kluwer Academic Publishers.
- Graff, G., A. Heiman, C. Yarkin, and D. Zilberman. 2003a. Privatization and Innovation in Agricultural Biotechnology. *Giannini Foundation of Agricultural Economics* 6 (3): 5-7.

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- Graff, G., S.E. Cullen, K.J. Bradford, D. Zilberman, and A.B. Bennett. 2003b. The Public-Private Structure of Intellectual Property Ownership in Agricultural Biotechnology. *Nature Biotechnology* (in press).
- Hall, B.H. 2002. "University of California at Berkeley and National Bureau of Economic Research." Paper presented to the International Conference on Technology Policy and Innovation, Kansai Science City, Japan, August 12-15, 2002.
- Hall, B.H., A.N. Link, and J.T. Scott. 2000. Universities as Research Partners. *NBER Working Paper No.* 7643 (April 2000). Cambridge, MA: National Bureau of Economic Research.
- Hicks, D. and K. Hamilton. 1999. Does University-Industry Collaboration Adversely Affect University Research? *Issues in Science and Technology* (Summer): 74-75.
- Kevles, D.J. 2002. Passing the Buck. The New Republic 227 (14): 33.
- Kjaergard, L.L. and B. Als-Nielsen. 2002. Association Between Competing Interests and Authors' Conclusions: Epidemiological Study of Randomized Clinical Trials. *British Medical Journal* 325: 249–252.

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Krimsky, S., L.S. Rothenberg, P. Stott, and G. Kyle. 1996. Financial Interest of Authors in Scientific Journals: A Pilot Study of 14 Publications. *Science and Engineering Ethics* 2 (4): 395-410.

- Mansfield, E. 1998. Academic Research and Industrial Innovation: An Update of Empirical Findings. *Research Policy* 26 (April): 773-776.
- Narin, F., K.S. Hamilton, and D. Olivastro. 1997. The Increasing Linkage between U.S. Technology and Public Science. *Research Policy* 26: 317-330.
- National Science Foundation (NSF). 1994. *National Patterns of R&D Resources: 1994*. NSF 95-304. Washington D.C.. Available at: www.nsf.gov/sbe/srs/s2194/start.htm.
- National Science Foundation (NSF). 2000. *National Patterns of R&D Resources: 2000 Data Update*. NSF 01-309. Washington D.C. Available at: www.nsf.gov/sbe/srs/nsf01309/start.htm.
- Poyago-Theotoky, J., J. Beath, and D.S. Siegel. 2002. Universities and Fundamental Research: Reflections on the Growth of University-Industry Partnerships. Oxford Review of Economic Policy (January 2002).
- Rochon, P.A., J.H. Gurwitz, C.M. Cheung, J.A. Hayes, and T.C. Chalmers. 1994. Evaluating the Quality of Articles Published in Journal Supplements Compared with the Quality of Those Published in the Parent Journal. *Journal of the American Medical Association* 272 (2): 108-113.
- Slaughter, S. and L.L. Leslie. 1997. *Academic Capitalism: Politics, Policies, and the Entrepreneurial University*. Baltimore and London: The Johns Hopkins University Press.

Tornquist, K.M. and L.A. Kallsen. 1994. Out of the Ivory Tower: Characteristics of Institutions Meeting the Research Needs of Industry. *Journal of Higher Education* 65 (5): 523–539.

U.S. Department of Agriculture, Economic Research Service (USDA-ERS). 2001. Agricultural Research Funding in the Public and Private Sector. Washington, D.C. Available at: www.ers.usda.gov/data/agresearchfunding/index.htm.

- Zucker, L.G., M.R. Darby, and J.S. Armstrong. 2002. Commercializing Knowledge: University Science, Knowledge Capture, and Firm Performance in Biotechnology. Management Science 48 (1): 138-154.
- Zusman, A. 1999. Issues Facing Higher Education. In American Higher Education in the Twenty-First Century, P. Altbach, R. Berdahl, and P.Gumport, eds., 107-148. Baltimore, MD: The Johns Hopkins University Press.

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Workshop Program · Appendix A

USDA/CREES/IFAFS Project

"Public Goods and University-Industry Relationships in Agricultural Biotechnology" and the Pew Initiative on Food and Biotechnology

EXPERT WORKSHOP ON

University-Industry Relationships and the Public Good: Framing the Issues in Agricultural Biotechnology

November 19-20, 2002 • Charles Hammer Conference Center • Research Triangle Park, NC

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TUESDAY NOVEMBER 19,	2002 • Forces Shaping University-Industry Relationships
Presiding: David Ervin,	Professor, Portland State University
10:00 AM – 10:10 AM	 Welcome and Introduction David Ervin, Professor, Portland State University Michael Rodemeyer, Executive Director, Pew Initiative on Food and Biotechnology
10:10 AM - 10:30 AM	The Changing Context for University-Industry Relationships in Agricultural BiotechnologyDavid Ervin, <i>Professor, Portland State University</i>
10:30 AM - 11:00 AM	 Typology of University-Industry Relationships Mark Crowell, Associate Vice Chancellor and Director, Office of Technology Development, University of North Carolina at Chapel Hill
11:00 AM – 12:00 PM	 University-Industry Relationships: Academic Scientists' Perspectives Molly Jahn, Associate Professor, Department of Plant Breeding, Cornell University Alan Jones, Professor, Department of Biology, University of North Carolina at Chapel Hill Harry Klee, Eminent Scholar, Department of Horticultural Sciences, University of Florida
12:00 PM - 1:00 PM	Open Discussion
1:00 PM - 2:00 PM	Lunch

	Presiding: Terri Lomax, 2:00 PM – 2:30 PM	 Professor, Oregon State University Preliminary Project Findings from University and Industry Interviews William Lacy, Vice Provost, University Outreach & International Programs, University of California at Davis 		
	2:30 PM – 3:00 PM	 Preliminary Findings from the Berkeley-Novartis Case Larry Busch, University Distinguished Professor, Department of Sociology, Michigan State University 		
	3:00 PM – 3:30 PM	Intellectual Property RolesDeborah Delmer, Associate Director, Food Security, The Rockefeller Foundation		
	3:30 PM - 3:45 PM	Break		
	Providing: Michael Pedemover, Pau Initiative			
Universitų-Industrų Relationships	3:45 PM – 4:15 PM	 Technology Transfer: A University Perspective Richard Cahoon, Associate Director, Patents and Technology Marketing, Cornell University 		
54	4:15 PM – 5:30 PM	Open Discussion		
	Presiding: Rick Welsh, Clarkson University			
	5:30 PM – 6:00 PM	 Rapporteur Bob Goodman, Professor, Department of Plant Pathology, University of Wisconsin at Madison 		
	6:00 PM – 8:00 PM	Reception and Dinner • Peter Pringle, <i>Journalist/Author</i>		
	WEDNESDAY NOVEMBER	20, 2002 • FRAMING THE ISSUES IN UNIVERSITY-INDUSTRY RELATIONSHIPS IN AGRICULTURAL BIOTECHNOLOGY		
	Presiding: Steven Bucco 8:00 AM – 8:45 AM	 la, Professor, Oregon State University University-Industry Research Relationships – Industry Views John Anderson, Monsanto Glenn Hicks, Associate Director, Plant Genetics, Exelixis Pharmaceuticals 		
	8:45 AM – 9:30 AM	 University-Industry Research Relationships - Critical views Sheldon Krimsky, Professor, Urban & Environmental Policy & Planning, Tufts University Hope Shand, Research Director, ETC Group 		
	9:30 AM - 9:45 AM	Break		

Presiding: Kate Clancy, *Wallace Center, Winrock International* 9:45 AM – 12:00 PM Breakout Discussions Breakout Group A Breakout Group B Breakout Group C Breakout Group D Breakout Group E

Presiding: Walt Armbruster, Farm Foundation

12:00 PM – 2:00 PM Lunch and Reports from Breakout Discussions

2:00 PM - 2:30 PM

Workshop Summary

- Michael Rodemeyer, *Executive Director, Pew Initiative on Food and Biotechnology*
- Terri Lomax, Professor, Oregon State University

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Workshop Participants · Appendix B

Speakers

John Anderson – Technology Development Manager, Monsanto	
Lawrence Busch – University Distinguished Professor, Michigan State University	
Richard Cahoon – Associate Director of Patents and Technology, Cornell Research Foundation, Cornell University	
Mark Crowell – Associate Vice Chancellor and Director, The University of North Carolina at Chapel Hill	
Deborah Delmer – Associate Director, Food Security, The Rockefeller Foundation	
Robert Goodman – Professor, University of Wisconsin, Madison	Pew Initiative on Food and Biotechnology
Glenn Hicks – Associate Director, Plant Genetics, Exelixis Pharmaceuticals	
Molly Jahn – Associate Professor, Cornell University	57
Alan Jones – Professor, The University of North Carolina at Chapel Hill	
Harry Klee – Professor, University of Florida	
Sheldon Krimsky – Professor, Tufts University	
Peter Pringle – Journalist/Author	
Hope Shand – Research Director, ETC Group	

Participants

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- Mike Burke Associate Dean, Oregon State University
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- Harold Coble Agronomist, USDA/ARS/OA, Office of Pest Management Policy
- Mark Conkling Vice President of Genetic Research, Vector Tobacco
- Kristin Dawkins Vice President for International Programs, The Institute for Agriculture and Trade Policy
- John Dodds Attorney, Dodds & Associates
- Martha Dunn Licensing Manager, Syngenta Biotechnology, Inc.
- Don Duvick retired scientist, Pioneer

- Paul Heisey Economist, Resources, Technology and Productivity Branch, Resource Economics Division, Economic Research Service, U.S. Department of Agriculture
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- Catherine Ives Licensing Associate, Office of Technology Transfer, Community Technology Fund, Boston University
- John King Economist, USDA Economic Research Service
- Stephanie Mercier Minority Staff Member, Senate Agriculture Committee
- Stephen Merrill Executive Director, Board on Science, Technology and Economic Policy, The National Academies
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Bryan Renk – Director of Patents and Licensing, Wisconsin Alumni Research Foundation

- Eugene Sander Vice Provost and Dean, College of Agriculture, The University of Arizona
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- James Siedow Vice Provost for Research and Professor of Biology, Duke University
- Kitty Smith Director, Resource Economics Division, Economic Research Service, USDA
- William Thompson Professor, North Carolina State University
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- Carol Mimura Associate Director, Office of Technology Licensing, University of California at Berkeley
- Michael Rodemeyer Executive Director, Pew Initiative on Food and Biotechnology
- Michael Schechtman Biotechnology Coordinator, U.S. Department of Agriculture