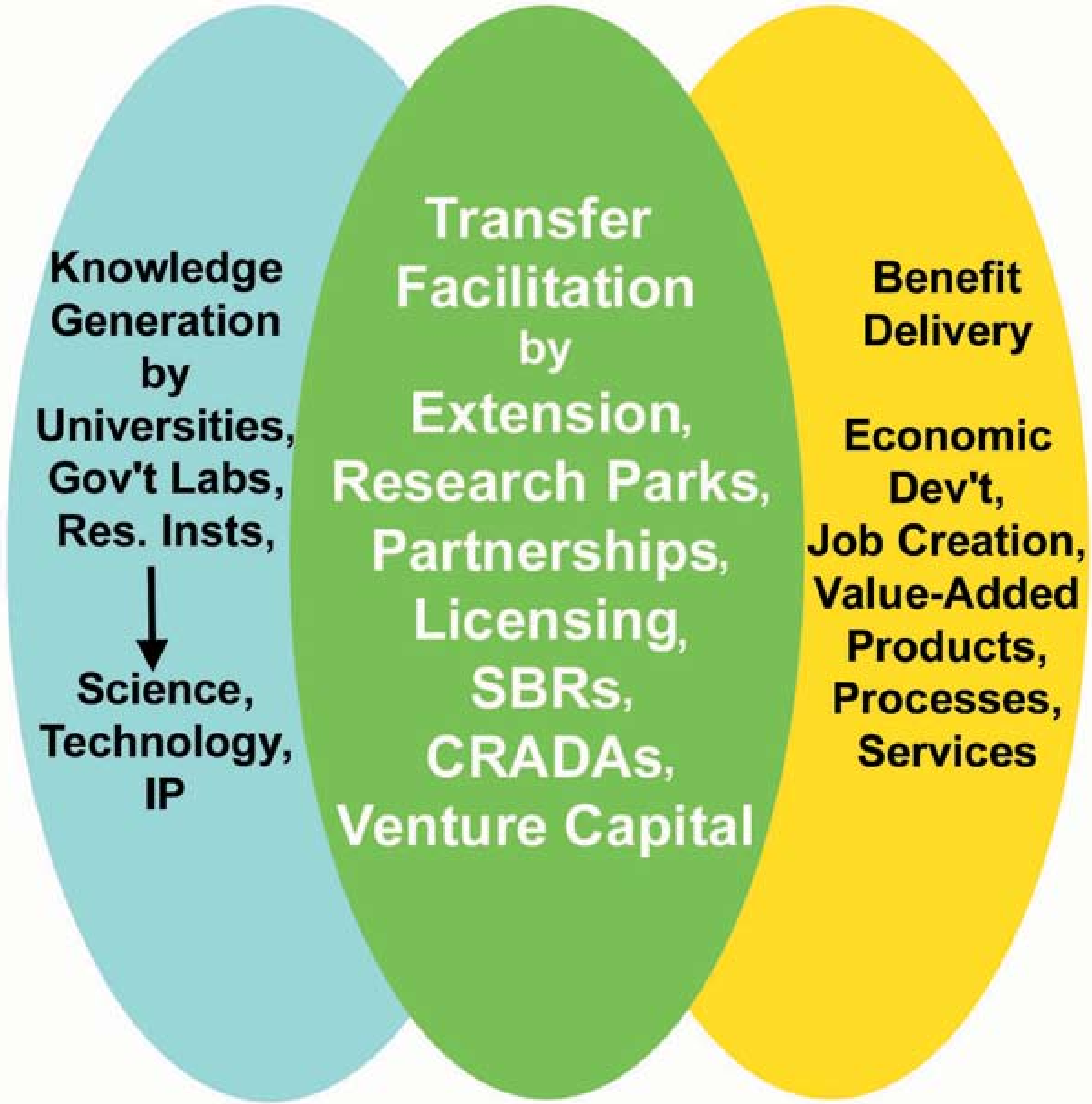
NABC Report 18



Agricultural Biotechnology:
Economic Growth Through New Products,
Partnerships and Workforce Development

Biotechnology: Economic Growth Through New Products, Partnerships and Workforce Development

2006

NABC Report 18

Agricultural Biotechnology: Economic Growth Through New Products, Partnerships and Workforce Development

Edited by
Allan Eaglesham and Ralph W.F. Hardy

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for exploring issues in
agricultural biotechnology

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NABC's eighteenth annual meeting—*Agricultural Biotechnology: Economic Development through New Products Partnerships and Workforce Development*—was hosted by Tony Shelton, Cornell University/New York State Agricultural Experiment Station, Ithaca/Geneva, NY, to whom we are most grateful. The success of the conference and its smooth operation resulted from his unstinting efforts.

Thanks are due also to the other members of the Organizing Committee for an excellent agenda and first-rate choice of speakers: Richard Brenner, Robert Fireovid and John Radin (USDA-ARS), Dan Fessenden (Cornell Agriculture and Food Technology Park), James Hunter and Bob Seem (Cornell University/New York State Agricultural Experiment Station), Steve Slack (Ohio State University), David Stern and Alan Wood (Boyce Thompson Institute), and Milt Zaitlin (Cornell University).

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And, on behalf of NABC, we thank Steve Slack for his exemplary guidance and leadership as NABC's Chair for 2005–2006.

Ralph W.F. Hardy
President
NABC

Allan Eaglesham
Executive Director
NABC

December 2006

PREFACE

The National Agricultural Biotechnology Council's eighteenth annual meeting (NABC 18)—*Agricultural Biotechnology: Economic Development through New Products, Partnerships, and Workforce Development*—was the first to focus primarily on vehicles for transfer of knowledge generated mainly in the publicly-funded sector to benefits. Knowledge generation by universities, government laboratories and research institutions produces science, technology and intellectual property (IP). Historically, agriculture has used the extension service to deliver benefits from this knowledge to farmers and consumers. During the past 25 years, the need to protect increasingly complex IP (such as biotechnology) has been recognized increasingly as a necessary first step for investment of risk capital to deliver benefits—economic growth, job creation, and value-added products, processes and services—resulting from generation of knowledge. A diversity of vehicles is being used to facilitate transfer, including research parks, partnerships, licensing, SBIRs, CRADAs, and venture-capital investment. At NABC 18, a wealth of examples was presented from the United States and Canada as well as from Europe, China, India and Brazil. In one case, the University of Wisconsin, there is almost complete segregation of knowledge-generation from transfer and from benefit-delivery, whereas, at the other extreme, in China all occur within the university. In general, transfer facilitation is moving from a major focus on economic benefits to considering other benefits as well. As experience continues to accrue, it is suggested that commonality will evolve in transfer facilitation. It is hoped that the information in *NABC Report 18* will prove useful in this evolution.

Briefly, NABC 18 focused on the following themes and related areas:

- Past successes, future prospects and hurdles
- Function and role of university-based research parks in economic development
- An up-close look at one research park—the Cornell Agriculture & Food Technology Park (CAFTP)
- Bridging the gap: From laboratory to commercial product

From presentations on past successes and future prospects, the impressive—but not well recognized—role of agricultural research in providing seminal advances in the life sciences is documented. For example, the initial research on RNA interference (RNAi), the basis of one of the 2006 Nobel Prizes, was a product of agriculture, although it was not recognized as such in the award. We need to better communicate the contributions of agriculture to broad knowledge generation.

Hosted by Cornell University June 12–14, 2006, NABC 18 had 110 attendees, with representation from eight countries. Activities on the Monday afternoon, early Tuesday morning and Wednesday morning took place on Cornell's Ithaca campus, and buses transported the delegates for Tuesday lunch and afternoon activities at the Cornell Agriculture & Food Technology Park (CAFTP) on the campus of the New York State Agriculture Experiment Station in Geneva, NY. The return to Ithaca included a stop to sample viniferous delights at the Chateau LaFayette Reneau Winery.

The speakers included scientists who have established spin-off companies, leaders of agricultural biotechnology parks in the United States and internationally, government and university administrators, and community and government leaders who have worked on economic development programs involving biotechnology. At the conclusion of the formal presentations, attendees convened in breakout sessions for further discussion of issues raised by the speakers and in Q&A sessions, and to make recommendations to policymakers.

This volume contains an overview of the meeting, a summary of the breakout workshops and the recommendations, and the presentations including those made during the banquet and in a supplementary session. Transcripts of the Q&A sessions and of a panel discussion are included. Video recordings of the presentations are available at http://www.nysaes.cornell.edu/ent/nabc/schedule.html.

NABC 19—*Agricultural Biofuels: Technology, Sustainability, and Profitability*—will be hosted by South Dakota State University and will convene May 22–24, 2007, in Brookings, SD. The activities will include tours of a large-scale ethanol plant and of a biodiesel-production facility. Further information may be accessed via http://nabc.cals.cornell.edu.

Allan Eaglesham
Executive Director
NABC

Ralph W.H Hardy
President
NABC

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PART I

Conference Overview

Agricultural Biotechnology: Economic Growth Through New Products, Partnerships and Workforce Development

Allan Eaglesham & Ralph W.F. Hardy
National Agricultural Biotechnology Council
Ithaca, NY

NABC's eighteenth annual meeting, hosted by Cornell University, convened in Ithaca and Geneva, NY, June 12–14, 2006. Delegates were welcomed to Cornell by Bill Fry (Senior Associate Dean of the College of Agriculture and Life Sciences), and by Steve Slack (NABC Chair 2005–2006/Ohio State University), Tony Shelton (NABC-18 Host/Cornell) and Ralph Hardy (NABC President). Activities on the Monday afternoon, early Tuesday morning and Wednesday morning took place on Cornell's Ithaca campus, and buses transported the delegates for Tuesday lunch and afternoon activities at the recently established Cornell Agriculture & Food Technology Park (CAFTP) on the campus of the New York State Agriculture Experiment Station, Geneva.

Presentations on past technology-transfer accomplishments and both national and foreign experiences in various structures that facilitate technology transfer provided a strong background for discussions on how public-sector research can produce economic growth through new products, partnerships and workforce development. Agriculture's track record for public good is impressive; technology transfer has been achieved through diverse methods. The presentations and discussions at NABC 18 provided guidance for the future structure of technology transfer from public-sector research to public good and commercial products.

Session 1—*Past Successes, Future Prospects and Hurdles*—comprised plenary presentations by Alan Wood (Boyce Thompson Institute, *Agricultural Research: Beyond Food and Fiber*), Peggy Lemaux (University of California and Berkeley, *Ag Biotech Pipeline: What's in the Lineup?*), Ralph Hardy[1] (NABC, *Research to Market/Public Good: Economic Perspectives*) and Deborah Delmer (Rockefeller Foundation, *Road Bumps and Pitfalls for Agricultural Biotechnology*). And presentations covering technology transfer in Canada, India, Brazil, China and Germany were made, respectively, by Keith Downey (Agriculture Canada, *Rapeseed to Canola: Rags to Riches*), K. Vijayaraghavan (Sathguru Management, *India:*

[1]In place of Roger Wyse (Burrill & Company) who was unable to attend.

New Products and Opportunities), Ana Claudia Rasera da Silva (Alellyx Applied Genetics, *New Perspectives for Ag Biotech in Brazil*), Zhanglian Chen (China Agricultural University, *Chinese Agricultural Biotechnology in the Field*) and Peter Welters (Phytowelt, *Globalization of European Biotechnology: Commercialization of Agbiotech Products Despite Political and Legal Restrictions*).

Alan Wood described a proposal for a National Institute for Food and Agriculture to enable the United States to maintain competitiveness in this field. Having invited NABC-member institutions to submit information regarding recent agricultural research beyond food and fiber with significant societal impacts, Wood described outstanding contributions to society under the headings *Energy, Food Safety/Diet, New Products, Animal, Health, Environment* and *Plant Biology.* Seventeen Nobel Prizes have been awarded to scientists involved in aspects of agricultural research, most of whom are not known to the public at large. The value and significance of US agricultural production and research must be more effectively communicated to the public and to legislators in order to improve understanding of the national and global importance of US agriculture, its breadth of impact and an appreciation of its many contributions to society beyond food and fiber, including human health and biobased products.

Peggy Lemaux pointed out that new applications of genetic engineering in agriculture are not limited by the technology. Progress is clouded by factors outside the control of scientists, particularly of academic scientists, like high regulatory costs and limited access to key technologies because of intellectual-property protection. Consumer-acceptance will also be important. It is likely that modern biotechnology will play an increasingly important role in other countries—China for example—where these issues are not likely to be key factors.

Ralph Hardy outlined methods for science/technology transfer to market to achieve public good. He provided public- and private-sector examples of venture capital for early commercialization of agricultural science and technology. Hardy emphasized that licensing income is likely to be relatively small and that the objective of technology transfer should be to maximize public good not to maximize financial gain to the institutional "home" of the invention. Evaluations by and of technology-transfer offices should use the public-good metric, not the income metric.

According to Debbie Delmer, the problems for biotechnology vary according to who you are—a large company that deals with important crops and developed-country farmers, a small private company, a public sector entity, university, national agricultural system or a CGIAR institution. It is difficult to judge the degree to which negative public perception remains a significant issue. Strong research programs on development of genetically engineered (GE) crops are in progress in China, India and Brazil. Even in the European Union, GE crops are now planted in a few countries. Some 10% of people say that genetic engineering of crops is great stuff and another 10% hate it, while in the middle is a vast disengaged majority who really don't care, including many farmers in the developing world. People are growing tired of the debate. "It's time to get on with it." Delmer also noted the importance of making IP available to developing countries and public-sector research.

The development of canola from rape-seed oil, described by Keith Downey, diversified Canada's agriculture base, eliminated dependence on imported vegetable oil and increased returns to producers while expanding markets at home and abroad. It resulted also in the establishment of a large rural-based, value-added oilseed-crushing and -refining industry. The story continues in that canola is a preferred biodiesel source for northern climates because of its low content of saturated fatty acids. Canola development continues, to better meet user needs.

India's economy is among the fastest growing in the world—6% to 8% annually over the past decade—according to "Vijay" Vijayaraghavan. On the other hand, growth in agriculture has been less than 2%. A national mission is in progress to revive the under-performing agriculture sector by enhancing farm production and food quality while reducing waste. The strategy includes attracting investments that will trigger high growth in agriculture and in the processed-food industry and partnering in global research initiatives that will help India to acquire as well as provide technologies.

In Brazil, the production of ethanol from sugar cane has increased three-fold in the past 25 years. The current average yield is 6,000 L/ha. However, in line with the Kyoto Protocols, a production increase of at least 3-fold again will be needed by 2010 to satisfy projected demand. This goal is achievable as a result of Brazil's scientific expertise in breeding and genetic engineering, to increase productivity of sugar cane as a crop and improve efficiency of ethanol synthesis.

The public debate in China on the safety of GE crops was "imported" from Europe, stated Zhangliang Chen. It is germane in particular to the improvement of rice productivity in that country, where GM varieties are in final field-trial stages. On the other hand, Peter Welters reported that the scare-mongering of anti-GM-activists in Europe is increasingly recognized for what it is. Examples showing benefits of applying genetic engineering to plants are finding acceptance by the general public. "We have only to inform people correctly and constantly about the progress and the benefits of this new technology. Millions of farmers worldwide can't be wrong."

In session 2—*Function and Role of University-Based Research Parks in Economic Development*—presentations were made by Ashley O'Sullivan (Ag-West Bio, Inc., Canada, *From Tools to Products: The Evolution of Saskatchewan's Agbiotech Cluster*), Allen Dines (University of Wisconsin, *From Equines to Economic Development: The Story of University Research Park*), Wim Jongen (Wageningen Business Generator, Netherlands, *Food for Innovation: The Food Valley Experience*) and Zhianglian Chen (Agricultural University, China, *The Chinese Experience in Innovation*).

"What is the bio-economy?" asked Ashley O'Sullivan. From the perspective of Ag-West Bio, it simply involves creating and capturing value from biological systems. The challenge and the opportunity for each region are the ability to understand and to effectively exploit global comparative advantages. The strategy at Ag-West Bio for Saskatchewan is twofold: (i) marketing their excellent bio-economic infrastructure, and (ii) identifying and targeting strategic opportunity sectors. Ag-West is probably the earliest example of a technology park focused exclusively on agriculture.

Allen Dines' story of the University Research Park in Madison provided an instructive case study of how favorable outcomes can arise from university-established parks focused on fostering commercialization of university research. Wisconsin has a long-term record in technology transfer; the irradiation of milk to produce vitamin D in the 1920s is a seasoned example. Recently, several companies have expressed interest in relocating to the Madison area as a result of opportunities resulting from association with the university-research environment.

The concept that science-based economical development is crucial for general economical development and competitiveness, according to Wim Jongen, begs the question of how to organize the process. The objective of the Food Valley cluster, developed in the Netherlands, is the creation of a network for innovation and business involving companies, research institutes, experimental facilities, incubators and public-private-partnership based R&D programs with the foci being food, health and nutrition. The initiative—by three city councils—has grown into a regional economic force.

Zhianglian Chen reported that, since 1991, the Chinese government has encouraged university professors to form companies. Even in public universities, a professor can run a business from her/his own laboratory, owning 100% of the company or shares thereof. Some professors have made large amounts of money. On the other hand, Chen expects that universities will continue to play a vital role in high-tech business development and innovation, making major contributions to a knowledge-based economy in China. This merging of universities and business was the most tightly coupled example described at the meeting.

Session 3—*An Up-Close Look at One Research Park: the Cornell Agriculture & Food Technology Park (CAFTP)*—took place at CAFTP as a "town hall" discussion moderated by Dan Fessenden (CAFTP). Brief comments from Michael Manikowski (Ontario County Development), Karen Springmeier (Finger Lakes Workforce Investment Board), James Hunter (Cornell University/New York State Agriculture Experiment Station), Susan Riha (Cornell) and Roger Williams (Cornell) helped to focus the discussion.

Dan Fessenden sketched a brief history of the New York State Agricultural Experiment Station in Geneva, NY, on the campus of which CAFTP is situated, and described the thinking that underpins the Park and the process whereby physical-plant infrastructure—a flexible technology facility—is now available for occupancy. It is envisaged that CAFTP will eventually occupy 70 acres of what was, until recently, apple orchards that had been "retired" from research use. Four start-ups, including agbiotech companies, occupy office space on campus and are expected to enter pilot production in the main facility in the near future. Ground-breaking is expected in 2007 of a USDA-funded grape-genetics research center.

Session 4—*Bridging the Gap: From Laboratory to Commercial Product*—comprised presentations from William Goldner (USDA-SBIR, *Vision, Opportunity, and Challenge: The USDA-Small Business Innovation Research Grants Program*), Richard Brenner (USDA-ARS, *Technology Transfer in the Agriculture Research Service*), Michael Adang (University of

Georgia, *From the Bench to a Product: Academics and Entrepreneurship*), Mary Pat Huxley (California Community Colleges, *The "Central Dogma" of Economic and Workforce Development*), Richard Broglie (DuPont, *Translating Discovery Research into Commercial Products*) and Paul Thompson (Michigan State University, *Technological Ethics in University-Industry Partnerships: The Best of Both Worlds?*).

Bill Goldner described the USDA's Small Business Innovation Research Program. This competitive funding program, authorized by Congress in 1982, stimulates and facilitates R&D by US-owned and -operated for-profit small businesses (<500 employees). All executive branch departments with extramural research budgets exceeding $100 million are directed by legislation to provide a 2.5% set-aside to fund SBIR. Rick Brenner reminded the audience that the USDA helps drive continuous innovation through science and technology by forming Cooperative Research and Development Agreements (CRADAs) with research institutions and the private sector. The Office of Technology Transfer in the ARS is key in facilitating these partnerships and in transferring research outcomes for broad beneficial use by the public and agricultural industries of the United States and other nations. Given recent concerns about rising petroleum prices, the United States will be increasing research emphasis on new, environmentally favorable crops for industrial uses representing new economic opportunities for farmers and reducing dependence on imported fossil fuels. There is renewed hope that the most prosperous era in American agricultural history is dawning to meet continuing and expanding national needs.

Mike Adang described his experience in translating research discoveries to a product via a new company that he founded: Insectigen. He discussed ethical conflicts between the role of the entrepreneur—which can be time-consuming—and the role of the professor with obligations to students, to postdocs, to research colleagues, and to others in the university milieu.

Mary Pat Huxley discussed development of the workforce in general and of the biotechnology workforce in particular. She remarked that the United States is not outpacing its competitors with as wide a margin as it did 40 to 50 years ago. Many workers are unable to meet new technical needs in the workplace, and incoming workers often fail to realize that innovation is t he driver of the US economy. Such innovation increasingly relies on workers having scientific, mathematical and technical ability, alongside workplace-competency skills.

Rick Broglie provided concrete examples of bridging "the valley of death"—*i.e.* transferring science and technology into commercial products. He concentrated on the work that is going on at DuPont Crop Genetics Research and Development, where they try to predict trends for agricultural production in the next 5–10 years. He sees growing demands for biobased fuels and materials, which with other factors, will drive their farmer customers towards more-intensive production systems. They use two complementary paths for product development: the transgenic, gene-discovery approach that has been used for products currently on the market, and, for more complex traits—*e.g.* balanced amino acids, increased energy availability via increased oil and decreased fiber content—a "new technologies" approach that may or may not involve genetic engineering. New traits have to be commercialized in high-yielding germplasm, and several enabling technologies are employed including molecular genetics; backcrossing can be made more efficient by using molecular markers to select lines with the background of the recurrent parent.

Paul Thompson suggested that technological ethics are today better served in the private sector than in the universities. If so, university-industry partnerships could have the result of improving the capacity for university-based science to address ethical issues, if they bring some of the norms and practices that are commonplace in the private sector into the university. Or they could have the result of transferring the relatively weak ethics performance of university science to the private sector. While we can hope for the better outcome, his suspicion is that university-industry partnerships are likely to produce the latter.

The banquet presentation was by Mark Crowell (University of North Carolina, *Knowledge Transfer and Economic Development: The Role of the Engaged University in the Twenty-First Century*) and a supplementary talk was given by Rick Welsh (Clarkson University, *Agricultural Biotechnology and University-Industry Research Relationships: Perceptions of University Scientists and Administrators and Industry*).

Mark Crowell discussed the function of the Association of University Technology Managers (AUTM), an international organization with about 3,500 members. Mirroring the global economy, 25% of the membership is outside North America and growing at 2½ times the rate of the US group. The AUTM's *Better World Project* is an attempt to show the impact of public-sector research that is not necessarily reflected in terms of licenses, patents and revenue. Twenty-five in-depth stories of university innovation have been collated demonstrating impact regardless of financial implications. A companion piece, *Reports from the Field*, contains a hundred similar stories in vignette form. These reports are being sent to all members of Congress and to agencies in Washington, DC, to promote understanding of the important roles academic research and technology transfer play in making our world a better place in which to live.

According to Rick Welsh—based on a recently completed study—industry funding generally brings modestly less basic and more excludable (*e.g.* patentable) research than does NSF or NIH funding. Industry is wary of the decline in the level of basic research at universities, but contributes to it through its funding relationships. This points to the importance to a number of parties of continuing to publicly fund basic research at universities.

In addition to Q&A discussions with audience participation at the conclusion of each session, breakout workshops were held, during which delegates, in smaller groups, had the opportunity to discuss further issues raised in the presentations, to raise other related matters and to make recommendations to share with policymakers. The Q&A sessions are included in this volume as is a summary of the workshops.

PART II

Breakout Sessions

Workshops Summary

SARAH NELL DAVIDSON
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University Park, PA

Three workshop sessions were held, with nine questions posed to help focus the discussions. Participants were encouraged to formulate recommendations on the basis of the presentations and discussions at the plenary sessions as well as at the workshops.

SESSION 1

Question 1: Should not-for-profit agencies, institutions and universities actively focus on economic and workforce development as part of their mission?

- Whether we believe that to be part of a university's mission or not, people who are supporting public universities are increasingly expecting it in return for investing in universities. Taxpayers support public universities and may expect a return in the form of economic development.
- Different parts of universities are affected in different ways. Certain colleges, certain departments, are on the firing line. Others see little impact on their faculty activities.
- The land-grant institution may be viewed as a three-legged stool with teaching, research and extension. Some see economic development as a logical fourth leg which should be encouraged via legislation.
- In California, specific economic workforce development occurred at the community college level after it was mandated by law in the mid-1990s.

Question 2: Have not-for-profit agencies, institutions and universities made an economic impact in the international, national, state, and local economies by creating new technologies/products/information?

- Although there is an inextricable link between new knowledge generated in universities and the harnessing of that knowledge to create economic growth and we should do everything we can to foster economic growth, the university's fundamental mission should not change: to educate, to expand knowledge through research, and to provide service. Economic development is part of the service.
- Economic impact should be a "side-product" of universities; consideration should more commonly be given by faculty to formal relationships with specialists in economic development.
- The traditional land-grant procedure is to give away technologies and not protect intellectual property. It needs to be redefined. Disagreement continues over the new model, the degree to which new knowledge should be channeled carefully and deliberately via protecting intellectual property.
- Many faculty lack the skills to convert research discoveries into products for the common good. Years ago, it was seen to be the responsibility of extension, but this is far more than extension.
- This philosophy is changing promotion and tenure policies. Economic development is written into the mission statements of many universities. Some high-level administrators have "economic development" in their titles.
- There are many other things in the public good besides economic development.
- The metric for economic development needs to be defined. Is it number of patents filed, how many technology transfers have occurred, other?
- Number of patents is a metric of something original that was granted but a poor indication of impact. Would a better measure of impact be number of technology-transfer transactions?
- The best metric is positive impact on quality of life, but how is it measured?
- Although it is essential for economic development to occur and to be a part of universities' programs, striking the right balance can be difficult ethically in terms of who assigns research priorities for faculty scientists with interests in IP, involved in start-up companies.

Question 3: Does biotechnology represent a new paradigm, or just a continuation of what land-grant universities have done?

- It depends on how biotechnology is defined. If the focus is on genetically modified crops then it is a new paradigm because public-perception issues are integral.
- Also, the time to develop a GM product is greatly increased because of regulatory strictures and the need to patent genes and new technologies.

- An obvious change is that before the 1980 Bayh-Dole Act, modifications to organisms couldn't be patented. There has been a huge proliferation of patents.
- If land-grant universities continue to focus on local problems for economic development, it will deplete international outreach efforts.

Question 4: How do we communicate the role agricultural biotechnology plays, not only in food, feed and fiber, but also in human health, energy, chemicals and the environment?

- In Europe they have tried to change the terminology.
- Demonstrating how important agriculture is in many areas of life beyond its traditional role may put it in a more positive light, with benefits for agricultural biotechnology.
- Agbiotech should be as transparent as possible.
- There is need for recognition by administration of the possibility that discoveries may contribute to economic development upstream.

SESSION 2

Question 1: What has the Cornell Agriculture and Food Technology Park (CAFTP) done right and what needs improvement.

- CAFTP has a flexible structure amenable for many purposes.
- It is managed by a corporation, therefore funds are not being diverted from the research-station budget.
- There is positive involvement of the community, which was engaged early in planning.
- It is unclear:
- – how long businesses can stay at the park,
- – what are the criteria for selecting tenants,
- – whether the necessary expertise is available,
- – whether the small faculty can keep ideas in the pipeline,
- – in bringing expertise in from outside, whether it is possible to compete successfully with other university parks,
- – whether transportation is adequate and if the distance to the Cornell main campus is problematical,
    - – how capital will eventually be accumulated,
    - – how many parks the area can support given the presence of other parks in the vicinity.
- Would it be easier to find resources within a larger area?

Question 2: Can CAFTP be replicated/modified for use at other universities?

- Yes, in that this park is, at least to some degree, a replicate of others; those involved in the planning visited other parks and implemented what seemed to work.

Question 3: What are the benefits/liabilities to the university of the CAFTP?

- It will help attract faculty and students and provide jobs for graduates.
- A job-training program at the local community college system would be mutually beneficial.
- Any financial losses will not directly affect the university; however, its reputation may be positively or negatively affected depending on the success of the park.

Question 4: What are the benefits/liabilities of having domestic/international collaborations between agtech parks?

- This will depend on the site of manufacture.
- NABC could play a role in facilitating interactions between parks.
- Complications may result from sharing proprietary information.
- Geneva needs a nearby airport.
- Collaborative projects moved elsewhere would give the impression of lack of commitment to the Geneva area.

It was recommended that CAFTP focus on community strengths: wine, value-added foods, and perhaps less on biofuels for example, which does not have a long-standing local base. Thus local investment may be encouraged through a PR campaign. The park may be marketed within the Syracuse/Rochester/Ithaca triangle. It is important to create a web of interactors; for example, advantage should be taken of the Johnson Business School on the Ithaca campus.

SESSION 3

Question 1. What are the negatives of a land-grant university focusing on economic and workforce development?

- It is unclear how the economic development mission will be viewed along with teaching, research and extension in the tenure process. Will impact on economic development be given equal weight as number of publications, grants obtained and teaching contributions?
- Workforce development is a component of teaching, whereas economic development is different.

- There may be intra-departmental conflict if some faculty members are more entrepreneurial than others.
- Will university faculty suffer identity crises? Can a university faculty member be an academic and an entrepreneur simultaneously?

Question 2: What are the barriers to economic and workforce development that will be encountered and how can they be overcome?

- There are few such barriers in today's climate.
- Adding economic development obligations may overburden university faculty; that burden would be lessened by having a support system in place.
- There is a limit to the objectives that a university can address efficiently. A division of labor may be needed. If too much emphasis is given to economic development, then teaching, for example, may be compromised.
- Being involved with economic and workforce development might bring university faculty more into contact with the private sector, with positive influence on the educational mission and preparation of students for workforce entry.

It was recommended that the people who need education be engaged to a greater extent in the process. Although we are constrained by our history and environment, it is time to take a new look, to break through tradition-bound ways of educating and explore new technologies that will better capture the "Net" generation. Quality control is an important issue, but it shouldn't be a barrier to implementing a better model.

Question 3: How can a land-grant university balance the need for institutional revenue and the public good?

- The whole burden should not fall on the university, which would be problematic in today's resource-poor environment.
- Public support for public universities is declining, increasing the time faculty spend in seeking alternative sources of funding.
- The Wisconsin Alumni Research Foundation and the University Research Park in Madison, Wisconsin, provides a good example of balance.

Substantial funding was recommended so that land-grant colleges can address pressing societal issues—energy, human and environment health, *etc.*—not just new funding, but new directions from government sources to focus on creating new knowledge-bases and new capabilities. Only then can agriculture address new approaches for society's long-term benefit in addition to focussing on today's or near-term needs for product development and commercialization.

PART III

CONFERENCE PRESENTATIONS

Past Successes, Future Prospects and Hurdles

Session I—Plenary Presentations

Agricultural Research: Beyond Food And Fiber

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During the early twentieth century, the business models for most industries were vertically integrated. For example, agriculture was only about food and fiber. As we moved into the twenty-first century the world changed radically, forcing industries to adjust. Vertical integration gave way to horizontal integration models. Agriculture has become integrated

Agriculture has become integrated into a variety of industrial sectors—pharmaceuticals, energy production, chemicals, etc.—resulting in new challenges and opportunities.

into a variety of industrial sectors—pharmaceuticals, energy production, chemicals, *etc*.—resulting in new challenges and opportunities. The following is a brief discussion of these challenges and opportunities with an emphasis on agricultural contributions to society beyond food and fiber. The principle influences for this discussion were:

- Thomas Friedman's national best-selling book *The World is Flat* (Friedman, 2005),
- a recent USDA-Research, Education and Economics (REE) Task Force report to Congress (Danforth *et al.*, 2004) supporting the formation of a National Institute for Food and Agriculture, and
- a personal survey of NABC institutions.

One of the strong influences for moving business models toward horizontal integration has been the shrinking world or, as Thomas Friedman would put it, "flattening" of the world. As outlined by Friedman (2005), rapid advances in technology and communications during the past two decades have led to a "smaller," more integrated world with greatly increased interaction and interdependence among nations. This has resulted in exceptional changes in the global market. For example, world commerce and trade have been significantly changed with the wealth created by three billion people in India, China and the former Soviet Union. In response to these factors, most major industries have made significant changes in their strategic planning, and agriculture is no exception. As the world has become smaller, US agriculture has been pressured to make changes to meet the new challenges of the global market.

Loss of Competitive Edge

Concurrent with these changes in the world scene, the competitive edge of American farmers relative to those of many other nations has begun to be eroded. Historically, US farmers enjoyed a leading role in world agricultural production, using innovative technologies and products to produce crops with higher yields at lower costs. However, many internal factors such as increased land prices, higher labor and fuel costs, and a vast array of other economic pressures are increasing the cost of production and reducing our competitive advantage.

Accordingly, today, US agriculture faces increased levels of international competition in the areas of food and fiber production. For instance, cotton producers in the Mississippi delta have expressed the opinion that Chinese and Indian agriculture are probably second only to the weather in determining US cotton prices. Considering another commodity, the United States is no longer the world's lowest-cost producer of soybeans (Danforth *et al.*, 2004), with Brazilian farmers selling soybeans at competitive prices; this cost advantage has resulted in midwest farmers cooperatively buying farms in Brazil to produce soybeans for export to the United States.

Ethanol production represents another example. Brazil can export sugarcane ethanol at prices below corn-based production in the United States (Ribeiro, 2005). Clearly, the flattening of the world has resulted in a redefinition of agricultural practices and global competition.

Genetic Engineering

In the past, US agriculture maintained its competitive advantage in the world market through science and technology, most recently through advances in biotechnology and, in particular, genetic engineering. With the commercial introduction of genetically modified (GM) plants more than a decade ago, US farmers were given a significant competitive advantage globally. In 2005, approximately 87% of soybean acreage, 52% of corn acreage, and 79% of cotton acreage in the United States were planted using GM seeds. The advantages of GM soybean, corn and cotton with herbicide resistance and *Bt* insecticides have led to acceptance of the technology in several global markets, resulting in more than $27 billion of global economic benefits (Brookes and Barfoot, 2005). However, as this technology is more widely accepted nationally and internationally, the competitive advantages to US farmers are being lost, resulting in price adjustments and concurrent diminishment of the previously enjoyed advantages of GM soybean, corn and cotton.

Further erosion of the economic advantage of GM plants has occurred as a result of their rejection by Europeans and a few other countries. It should be kept in mind that, while GM plants have been profitable to those in the agricultural industry, consumers have never realized any economic advantage from buying GM foods. Furthermore, because many of the companies selling GM seeds also sell chemical herbicides and insecticides, the ecological and health benefits of GM foods, as compared to those produced through alternative practices, have not been aggressively explained to the public. Hence, the general consumer public has not been moved to embrace GM foods as positive technologies.

Despite dwindling economic incentives, there remain several non-pecuniary advantages to the use of herbicide tolerance and insecticide biotechnologies. Farmers use these products because of their convenience, value, simplicity and relative heath/environmental safety compared with the alternatives (Marra and Piggott, 2006).

Confronted with the economic pressures of increasing international competition, diminishing economic value in some of the current agricultural technologies, increasing costs of labor, land and fuel, and poor consumer acceptance of GM products, the US farming industry is facing significant changes. In the past, US agriculture has used advances in science and technology to maintain healthy and competitive business environments. However, since the 1970s, public funding for agricultural research has been stagnant in real terms. Why has this occurred? Well, our grocery stores are well stocked with inexpensive food, and Americans pay a lower percentage of their gross domestic product for food than does any other developed nation. Fewer than 2% of Americans are involved in agriculture, compared with approximately 40% of the world population. And last but not least, the representatives of farming states are a minority in the US Congress.

A new granting agency, the National Institute for Food and Agriculture (NIFA), would fuel the technological advances required to keep US agriculture strong and competitive.

NIFA Proposed

Despite these negative factors, several members of Congress have been very concerned about the future of US agriculture and the trends in international competition. They called for a USDA REE Task Force to consider the possible formation of new National Institutes for Agricultural Research. After several months of interviews, meetings and deliberations, the committee recommended that Congress create a new granting agency, the National Institute for Food and Agriculture (NIFA), which would fuel the technological advances required to keep US agriculture strong and competitive. As of the time of this writing, NIFA has not been created.

Table 1. Recent advances in agriculture research by NABC-member institutions.

ENERGY
Corn-based ethanol production systems
Switchgrass biomass energy conversion

FOOD SAFETY/DIET
Lactose-free milk products
Vaccine development against *Campylobacter*
Lactococcus lactis resistance to bacteriophage
Human skeletal research
Enhanced sorghum germplasm
Vitamin-D fortification of cheese
Rapid detection of food-borne pathogens
Replacing antibiotic treatments of poultry
Eggs enriched with omega-3 fatty acids
Plant-derived edible vaccines
Comparative cattle-human genome mapping
Porcine xenotransplantation and drug production
Medical properties of arid-plant compounds

NEW PRODUCTS
Soy oil-based inks
SuperSlurper; high absorbant starch formulations
Bovine growth hormone
Canine parvovirus vaccine
Hybrid striped bass
Feline leukemia vaccine
Megalac fat utilization by lactating cows
Control of fescue toxicosis in beef
Diagnosis of feline immonodeficiency virus
Research on articular cartilage
Vaccines for equine influenza and strangles
Mastitis prevention and management

HEALTH
Tests for avian influenza
High production of proteins in insect cells
Elastomeric absorbable polymers
Biolistic gene gun
Mouse model for asthma
Human fertility assessment
Improved amino acid composition of crop plants
Poultry model for human autoimmune diseases
Isoflavonoid content in corn
Taxol biosynthesis pathway and genes

ENVIRONMENT
Controlled eutrophication remediation
Transgenic fish industry risk
Impact of global warming on agriculture
Remediation of radionuclides
No-till crop production
Enviropig™ utilization of phosphorus

PLANT BIOLOGY
Automated plant tissue-culture system
Peach-tree pest resistance
Sequence of the peach genome
Long-term storage technology
Cold response pathways in plants
Papaya ringspot virus resistance
Soybean resistance to *Phytophthora sojae*
Resistance to barley yellow dwarf virus
Floral scent research
Sequencing the rice genome
Insect resistance to *Bt* proteins
Engineering wheat flowering time
Strawberry breeding
Winemaking technology
Porcine cloning
Improved grain handling
New selectable markers in plant breeding
Maize genome sequencing
Plant resistance to the herbicide dicamba

NABC member institutions were solicited to submit information regarding recent agricultural research beyond food and fiber with significant societal impacts.

Societal Contributions

During the course of the USDA study, it became clear that a new institute would garner little public support based solely on food and fiber issues, partly because the benefits of agricultural research beyond food and fiber are not generally recognized by either the public or legislators. Therefore, NABC member institutions were solicited to submit information regarding recent agricultural research beyond food and fiber with significant societal impacts. A general description of the submissions received is listed in Table 1, revealing some outstanding contributions to society.

Biofuels

One such area of impact is biofuels, which, because of the current energy crisis in the United States, have become an important topic in US agriculture. In recognition of this, biofuels and energy sustainability will be the subject of the NABC meeting to be held at South Dakota State University in 2007. With close to a hundred ethanol plants and an annual capacity of nearly 4.5 billion gallons (Karnowski, 2006), agriculture is beginning to have an impact on US energy problems. About 39% of ethanol capacity is farmer-owned. Another thirty-five ethanol plants and nine expansions—with a combined capacity of more than 2.2 billion gallons—are being built in 2006.

Currently, 90% of the US ethanol production uses corn kernels as feedstock, contributing to a decrease in corn exports and a further decline in the agriculture balance of trade. In the first quarter of 2006, agricultural exports exceeded imports by only 5%, and corn prices rose from $2 to $2.50/bushel. Clearly, as oil prices continue to increase, corn and ethanol prices will also increase, as will the acreage of corn planted.

Approximately 2% of today's transportation fuels are derived from biomass and blended fossil fuels; Shell Oil has predicted that "the global market for biofuels such as cellulosic ethanol will grow to exceed $10 billion by 2012" (Greer, 2005). A recent study funded by the Energy Foundation and the National Commission on Energy Policy, entitled *Growing Energy: How Biofuels Can Help End America's Oil Dependence*, concluded that, if the United States follows an aggressive plan to develop cellulosic biofuel, farmers could see profits of $5 billion/year by 2025, with the need to import Persian Gulf oil decreased by two-thirds. At the same time, increased biofuel usage could reduce US greenhouse-gas emissions to 1.7 billion tons/year (22% of 2002 emissions) (Greene *et al.*, 2004).

As the United States has been forced to develop new energy strategies, the federal government and general public, unlike most areas of agriculture, have taken a serious interest in the biofuels industry. In order to promote the industry, the federal government currently subsidizes ethanol at $0.51/gallon. In addition, because of the cheap sugarcane ethanol available from Brazil, the US government has placed importation tariffs on ethanol. According to Kenneth Cook, president of the Environmental Working Group, corn is America's No. 1 subsidized crop (Grist, 2006); the federal government paid $37 billion in corn subsidies between 1995 and 2003. These actions point to the long-term importance that biofuels will play in future US energy plans.

In the meantime, a debate continues over the scope and impact of biofuels, their sustainability, and their potential impact on greenhouse-gas emissions. Part of this debate centers on the use of starch vs. cellulosic feedstocks and fermentation vs. gasification/syngas processes. In addition, there are debates regarding food vs. fuel consumption, price supports and import tariffs. The bottom line for US agriculture is that biofuels hold great potential value for the nation, socially, environmentally and economically. Hopefully in the next few years the scientific, economic and political issues surrounding biofuels will be resolved. Clearly, the biofuels industry will continue to be a growing segment of the US farm industry because of contributions to energy security, potential to reduce greenhouse-gas emissions, and support for agriculture (Koonin, 2006).

Biobased Industrial Materials

While biofuels and prices at the gas pump have been responsible for a public recognition of solutions to energy problems through corn, the public is much less aware of other industrial uses of farm crops in replacing petroleum imports. For instance, corn sugar and other agricultural raw materials are also being used to replace petroleum-based products to produce polyhydroxyalkanoate (PHA) plastics. In February of 2006, Archer Daniels Midland Company (ADM) and Metabolix announced that ADM will build the first commercial plant to produce a new generation of natural plastics that are eco-friendly and based on sustainable, renewable resources; the plant will have a capacity of 50,000 tons/year. Corn feedstocks are also being used to produce the polyester fabric Sorona® and polylactic acid (PLA) plastics. These are just three of the many manufactured goods for which plant-derived materials can be substituted for the petroleum products required hitherto for their production.

Contributions to Healthcare

In addition to prices at the gas pump, the American public is particularly interested in scientific advances in human health. Agricultural research at NABC and other agricultural research institutions is also making important contributions in the area of human health. Americans pay a higher percentage of their gross domestic product for healthcare than does any other developed nation (Cowling *et al.*, 1996). Many such advances have their foundations directly or indirectly in the findings of studies originally aimed at agricultural problems. For instance, using an animal model, Michigan State University veterinary researchers are using biotechnology to find the genes responsible for human asthma (Ewart *et al.*, 2000), which currently affects about 20 million Americans (ALA, 2006). These studies, which are elucidating the common molecular pathways that result in asthma, can open the way to treatments directed at the basic mechanisms of this disorder.

The baculovirus expression vector system (BEVS) is now used in thousands of research laboratories and more than seventy commercial licenses have been issued

A procedure now widely used to produce proteins of medical importance was originally discovered by entomologists at Texas A&M University in the course of studies on the use of naturally occurring insect viruses as alternatives to chemical insecticides. They discovered a method for introducing foreign genes into insect viruses and producing large amounts of foreign protein when the virus replicated in insect cells (Smith *et al.*, 1983); the baculovirus expression vector system (BEVS) is now used in thousands of research laboratories and more than seventy commercial licenses have been issued (TAMU, 2006). The BEVS has been used to produce many pharmaceutical proteins including vaccines to treat Hong Kong "bird-flu" virus and SARS; most recently it was used to produce a highly effective vaccine against human papilloma virus, a known cause of cervical cancer.

Other human vaccines are also being produced in agronomic plants. Worldwide, two billion humans are infected with hepatitis B and an estimated one million die each year from it and its complications (HBF, 2006). Researchers at the Boyce Thompson Institute and Arizona State University have developed plants that produce several recombinant proteins including vaccines against Norwalk virus (Mason *et al.*, 1996) and hepatitis B (Thanavala *et al.*, 1995).

Tremendous advances in the assessment of fertility have been made by scientists at South Dakota State University through the development of the sperm chromatin structure assay (SCSA) (Evenson and Wixon 2006). Using bovine sperm models, these researchers developed the first computerized, instrument-based test capable of measuring the genetic integrity of thousands of sperm cells in just seconds. More than 10% of US couples experience infertility problems (WebMD, 2006), and this method, which can be used to rapidly measure abnormalities that relate to defects in paternal genes, is now becoming widely used at human fertility clinics.

Researchers at Washington State University are elucidating the enzymes and processes involved in taxol biosynthesis. Taxol, a drug isolated from the bark of the slow-growing Pacific yew in the early 1960s, has been proven effective in the treatment of breast, ovarian and other cancers. The researchers are in the process of determining the metabolic pathway of the drug, isolating the pathway genes, and investigating the use of yew tissue culture as a means of producing the drug (Jennewein *et al.*, 2004). The development of a high-yielding, low-cost production system for taxol would be a major accomplishment.

A plant physiologist at the Boyce Thompson Institute discovered that vitrification (a type of sugar crystallization) is responsible for long-term maintenance of seed viability. The vitrification protects seed proteins from denaturation and inactivation (Sun and Leopold 1994). This protective factor has been applied to many other proteins. Most recently it was discovered that insulin could be stabilized by vitrification, making it possible to replace injection therapy with inhalation therapy (Potera, 1998). According to the American Diabetes Association approximately 21 million US adults and children deal with diabetes every day.

Cornell University researchers invented the gene gun, a "biolistic" method of transforming plant tissue by shooting DNA-coated metal particles into cells.

Technological Advancements

Agricultural research has made many contributions to biotechnology beyond enhancing food and fiber production. For example, Cornell University researchers invented the gene gun, a "biolistic" method of transforming plant tissue by shooting DNA-coated metal particles into cells. It allowed the transformation of plant species that at the time were recalcitrant to transformation by the widely utilized Ti-plasmid method (Ye *et al.*, 1990). Having been used to successfully transform agricultural as well as non-agricultural plants, animal cells, insect and fish embryos, algae, fungi, pollen, bacteria, and intracellular organelles, it has proven to be a very significant technological advancement in biotechnology.

Another extremely significant agriculture-based technology that promises to have a great impact on society is the discovery of RNA silencing in plants through RNA interference (RNAi). Discovered initially by researchers at the John Innes Centre (Baulcombe, 1996), this has opened the door to blocking the expression of nearly any eukaryotic gene. The potential uses, particularly in the treatment of human diseases, are enormous and a large number of human clinical trials testing RNAi-based drugs are currently underway. The 2006 Nobel Prize in medicine was awarded for the discovery of RNAi; however, the vital groundwork in plants was ignored.

Spreading the Word

These are a few of the more recent examples of significant contributions to society through agricultural research with application beyond food and fiber production. Except for possibly the plant-made vaccines, the general public and—possibly more importantly—Congress are unaware of these products of agricultural research. The agricultural industry does not have a lobbying group such as the health industry's Research!America (www.researchamerica.org), which refers to itself as "an alliance for discoveries in health" and advertises the latest discoveries in health science, particularly to legislators. Research!America claims that its educational activities are responsible for the recent doubling of the NIH budget. But, if Research!America were to advertise the new human papilloma virus vaccine or the new insulin-inhaler therapy, the key contributions of agricultural research would probably not be emphasized; to the best of the author's knowledge, only one newspaper, the *Ithaca Journal*, has carried a report of the agricultural connection to the insulin inhaler technology to the general public.

The agricultural community would benefit greatly by emulating the public relations strategy of NASA's space program. NASA promotes its research by advertising and promoting discoveries and products that have affected society beyond space travel (NASA, 2006). Among the dozens of spin-off products and technologies are charged coupled device (CCD) chips for digital imaging breast biopsies, a device to control chronic pain, new golf-ball designs, enriched baby foods, water-purification systems, freeze-dried food technology, home-security systems, smoke detectors, flat panel television sets, *etc*. As briefly listed above, agricultural research has similar spin-off products that could be used to enhance the public's recognition of its broad value to society beyond food and fiber.

When it comes to recognition of scientific value, the most widely accepted measure of excellence has been the Nobel Prize awards. In agricultural academic circles, the awards to Wendell Stanley for plant viruses in 1946, to Norman Borlaug (the "father of the Green Revolution") in 1970, and to Barbara McClintock for mobile genetic elements in 1983 are well known. Most of the additional fourteen awards listed in Tables 2 and 3, involving discoveries in the plant and animal sciences—with significant impacts in other areas of human health and well-being—are not generally recognized by the public.

Table 2. Agricultural research in plants: Nobel Prize awards.

1910	Otto Wallach	Chemistry	Plant smells and tastes
1915	Richard M. Willstatter	Chemistry	Plant pigments, especially chlorophyl
1930	Hans Fischer	Chemistry	Structure of haemin & chlorophyl
1937	Albert Szent-Gyorgyi	Physio/Med	Structure of vitamin C
1937	Paul Karrer	Chemistry	Carotenoids, flavins & vitamin A
1945	Artturi I. Virtanen	Chemistry	Nutrition & fodder preservation
1946	Wendell Stanley	Chemistry	Plant viruses
1949	John Boyd Orr	Peace	Global production and distribution of food
1950	Robert Robinson	Chemistry	Plant products: alkaloids
1961	Melvin Calvin	Chemistry	Carbon pathway: photosynthesis
1970	Norman E. Borlaug	Peace	The Green Revolution
1983	Barbara McClintock	Physio/Med	Mobile genetic elements

Table 3. Agricultural research in animals: Nobel Prize awards.

1966	Peyton Rous	Physio/Med	Rous sarcoma virus induced tumors in chicken
1975	Dulbecco, Temin & Baltimore	Physio/Med	Transformation via RNA-dependent DNA polymerase
1989	Bishop & Varmus	Physio/Med	Cellular origin of retroviral oncogenes
1990	Murray & Thomas	Physio/Med	Organ and cell transplantation
1997	Stanley Prusiner	Physio/Med	Prions: scrapie of sheep

While many scientists are familiar with the Rous sarcoma virus and the Nobel Prize awards for research with this virus, few realize that it was an agricultural research problem. The Rous sarcoma virus, which affects chickens, served as an ideal model for many important discoveries including the first identification of viral-induced tumors and the discovery of RNA-dependent DNA polymerase. Obviously, research on this chicken disease has had significant impact in the field of human-cancer research.

The public is also aware of mad cow disease (bovine spongiform encephalopathy, BSE) and, to lesser degrees, of kuru and Creutzfeldt-Jacob diseases. Stanley Prusiner was awarded a Nobel Prize for his discovery that these diseases are mediated by prions. Less well known by the public is that the discovery of prions and their diseases began with research on scrapie disease of sheep, another agricultural research problem that led to significant contributions to human health.

In Conclusion

Agricultural research in the United States continues to contribute substantially to feeding the world and in making significant societal contributions beyond food and fiber. In this changing world, strategic planning in US agriculture needs to become more global and inclusive in nature. And, in this flattened world, there is need to increase investment in the development of new products and technologies in order to keep US agriculture strong and competitive and to move the agricultural sciences to the next level.

This could lead to an understanding of the national and global importance of US agriculture and its breadth of impact, and an appreciation of its many past and future contributions to society beyond food and fiber.

To achieve these goals, the value and significance of US agricultural production and research must be effectively communicated to the public and to legislators. This could lead to an understanding of the national and global importance of US agriculture and its breadth of impact, and an appreciation of its many past and future contributions to society beyond food and fiber.

And finally, I think it is worth considering that, from a global standpoint, discoveries by US agricultural research can play a role in improving the productivity of subsistence farmers and combating hunger in developing countries; well-fed populations foster political stability and can contribute to our national security.

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Dr. Wood's research defined the interactions of the components of the cowpea mosaic and bean pod mottle viruses, developed methods for purification and characterization of fungal viruses, and elucidated the molecular biology of insect viruses. In 1989, he conducted the first US field release of a genetically engineered virus in Geneva, New York, which led to the optimized production of pharmaceutical proteins with insect viruses.

Based on his patented discoveries, he was a co-founder and chief scientific officer of AgriVirion, which produced pharmaceutical proteins in insect larvae. He is a member of Phi Beta Kappa, Gamma Sigma Delta and Sigma Xi, and was awarded a Fulbright Fellowship in 1981.

Ag Biotech Pipeline: What's in the Lineup?

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Throughout the nineteenth century, heredity remained a puzzle, even to scientists. How was it that after crossing two plants with different characteristics, you often got a plant with traits that were not identical to those of either parent? These questions intrigued Charles Darwin. He realized that these variations were the raw materials for natural selection. Conversely, uniformity from one generation to the next was the basis by which long-term effects were maintained. But Darwin was unable to decipher the underlying principles by which variation occurred on the one hand and uniformity was the norm on the other (Tompkins and Bird, 1973).

When Darwin published *Origin of Species* (Darwin and Appleman, 1991), Gregor Mendel was busy at work in a secluded monastery, occupied with the study of natural variation in peas. In this endeavor he was able to gain the first insights into the biological machinery behind heredity. His focus was to better understand what kept species distinct and what allowed them to be different following crosses. Studying these questions using natural variation in peas, Mendel gained an appreciation for the potential power of genetic manipulation applied to plants of agricultural importance. This work was extended by the findings of Luther Burbank (1907), a plant breeder whose prodigious production of new varieties of fruits, flowers, vegetables, grains, and grasses moved plant breeding into a more sophisticated science driven by an appreciation of genetics.

The use of genetics to modify plants and animals for agriculture moved into the current era with the identification by James Watson and Francis Crick (1953) of DNA as the element responsible for Mendel's wrinkled peas. This finding formed the platform for the development of recombinant DNA methods, first shown by California scientists Stanley Cohen and Herb Boyer who demonstrated a mechanism for moving functional DNA between unrelated organisms (Chang and Cohen, 1974), commonly referred to as biotechnology, recombinant DNA (rDNA) or genetic engineering.

Commercial Use of Genetic Engineering in Agriculture: What's Out There Now?

The first use of genetic engineering to modify plants was reported in tobacco in 1983 (Bevan *et al.*, 1983) and the first commercial genetically engineered (GE) crop, the FlavrSavr™ tomato, was developed by a California company, Calgene (http://www.accessexcellence.org/RC/AB/BA/Flavr_Savr_Arrives.html). Although the tomato was taken off the market, other GE crops were commercialized, most notably in large acreage crops like canola, corn, cotton, soy and, most recently, alfalfa. If success is measured by the increase in global acreage of these GE crops or their acceptance by farmers, certainly they have been successful. In 2005, the billionth acre was planted (James, 2005) by one of 8.5 million farmers in twenty-one countries. Most of the acreage is in the United States and almost none is in Europe. In the former, the adoption of herbicide-tolerant (HT) soybean represents 87% of total US acreage and HT cotton is at 60% (Fernandez-Cornejo and Caswell, 2006). Insect-resistant (*Bt*) cotton represents 52% and *Bt* corn 35% of total cotton and corn acreage, respectively. A few minor-acreage GE crops have met with commercial success: papaya, certain types of squash and sweet corn.

Acceptance by consumers has not come so easily. In a 2005 poll, 50% of US consumers opposed genetic modification (*i.e.*, genetic engineering) of plants and 33% strongly opposed it (http://pewagbiotech.org/resarch/2005update). Consumers were even more uncomfortable with genetic engineering of animals: 56% opposed GE animals and 66% opposed animal cloning. Despite the fact that consumers were opposed to genetic engineering of plants, 58% of US poll respondents—as recently as October 2005—weren't even aware that GE foods are being sold in grocery stores, an interesting dichotomy. Despite the majority of Americans admitting they have little knowledge of the regulatory structure governing GE food (55% in September 2004; http://pewagbiotech.org/research/2004update/2004summary.pdf), the majority of Americans (87% in July 2003; http://lists.iatp.org/listarchive/archive.cfm?id=79397) were confident that the food they eat is safe. Overall, these figures raise serious questions about the current state of consumer acceptance of foods containing GE ingredients and just exactly what is the nature of the issues they have with GE foods.

Use of Genetic Engineering in Agriculture: The Future?

Despite the large acreage, the diversity of GE crops and traits in commercially released varieties is limited. Nearly all major-acreage, commercial releases of GE crops are based on either insect protection via genes from *Bacillus thuringiensis* or herbicide tolerance, predominantly to Monsanto's Roundup® herbicide. More recently, stacked versions of these traits have been released, for example maize engineered for resistance to rootworm and European corn borer and tolerance of Roundup®. In addition, with the exception of GE papaya, which was developed by the public sector, all commercial varieties on the market in 2006 come from the private sector.

Insect-resistance and herbicide-tolerance traits are focused on improving life for the farmer. But, if used responsibly, these improved agronomic traits can also be beneficial to the environment, by increasing crop yields through the reduction of losses to insects, disease and weeds. This has been most dramatically demonstrated with decreases in insecticide applications with *Bt* cotton (Benbrook, 2004; Sankula *et al.*, 2005). Estimates of whether herbicide use has increased or decreased vary depending on the particular crop, the environment in which it was grown and the calculation method (*ibid.*). Despite the disagreement on the amount of herbicide used in GE vs. conventional crops, it is clear that there has been a shift in the herbicides used to more environmentally friendly types. It is also true that they are benefiting from the ease of application of herbicide to GE crops.

But what do end-users and consumers think about the future of this technology and where it might be most reasonably applied? In September 2004, Pew Trust poll (http://pewagbiotech.org/research/2004update/) respondents were asked about possible applications (Table 1). Clearly, some products of the technology were viewed more favorably than others. Producing more-affordable industrial compounds in plants, reducing the cost of fish such as salmon, creating fruits and vegetables that last longer and having beef with less fat were those applications that appeared least favorable. But consumers were in favor of producing more affordable pharmaceuticals using plants, although not by using animals. Also, reducing the need for pesticides, creating less-allergenic peanuts and developing vegetable oils with heart-healthy fats were viewed relatively favorably. One of the most interesting questions related to whether it is a "good or bad reason to genetically modify plants and animals" to "expand our understanding of science and nature": 46% of respondents said yes and only 10% said no.

Table 1. Are these good or bad reasons to genetically modify plants or animals?

	Very good	Very bad
	(%)	
To reduce the need to use pesticides on crops	43	12
To reduce the cost of fish like salmon	21	27
To produce more affordable pharmaceuticals using plants	54	8
To produce more affordable pharmaceuticals using animals	23	29
To produce more affordable industrial compounds using plants	2	17
To create types of grass that require less-frequent mowing	39	22
To create fruits and vegetables that last longer	27	30
To produce beef with less fat	27	32
To develop heart-healthy vegetable oils	41	18
To create hypo-allergenic peanuts	42	15
To expand understanding of science and nature	46	10

Certainly from a casual look at the scientific literature, scientists are utilizing the modern methods of genetically engineering organisms, coupled with genomic information, to gain in-depth understanding of living organisms. This information has led to a practice referred to as marker-assisted breeding. The term is used to describe the application of classical breeding methods coupled with genomics to create crops and animals with different characteristics resulting from new information gained about the location and function of genes. This information is normally determined or validated using the tools of recombinant DNA either to up- or down-regulate genes in the recipient organism. Although the technology uses information developed through the use of genetic engineering to read and manipulate the genome to determine function, the genetic information of the plants is not directly modified using recombinant DNA technology.

What's the Lineup in the Ag Biotech Pipeline?

The technologies used for marker-assisted selection can be successful for certain traits and certain crops and animals, given a long timeframe. However, when there is a desire to control precisely when and where a gene is expressed to achieve a certain outcome, manipulating these traits will not be achievable through such methods. Examples might include changes that require genes from other organisms, like insect-resistance or herbicide-tolerance genes from a bacterium, or other modifications that require genes to be linked to specific regulatory elements to control exactly when and where they are expressed, like genes mitigating allergenicity or delaying ripening that need to be altered only in the edible parts of the plant. These traits may be achieved by using antisense or gene-silencing mechanisms.

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Although commercialized GE crops are limited in traits used, proof-of-concept for many other traits has been reported. These can be divided into a number of categories: pest resistance, improved agronomic performance, tolerance to environmental stresses, increased food, feed and environmental quality, and medical and other applications.

Pest Resistance

A number of examples demonstrate the capability to improve the performance of crops through protection against pests. Starting in 1845, late blight disease attacked the potato crops that fed the densely populated island of Ireland, resulting in the infamous Irish potato famine. Now, with the globe much more crowded, potato experts report that the same disease, caused by the fungus *Phytophthora infestans*, is returning. But scientists, looking in the genome of a wild Mexican potato, discovered a gene that, when engineered into cultivated potato, allows the potato to survive exposure to the many races of *P. infestans* (Song *et al.*, 2003). Although GE potatoes show promise in resisting late blight, in May 2006 the world's largest chemical company, BASF, relinquished its plans for a GE-potato field experiment in County Meath (http://www.gmfreeireland.org/potato/), demonstrating the fear with which some European governments view GE crops, even if they address serious agricultural problems.

Another example is the identification of a native gene, *Mi*, in tomato that protects against root-knot nematodes (Milligan *et al.*, 1998). Surprisingly, at the time the gene was cloned, they discovered that the gene most similar to *Mi-1.2* is *Prf*, another tomato gene required for resistance to the bacterial pathogen *Pseudomonas syringae.* It turned out that the Prf and Mi-1.2 proteins share several structural motifs, including a nucleotide-binding site and a leucine-rich repeat region (NBS-LRR), characteristic of a family of plant proteins required for resistance to viruses, bacteria, fungi and nematodes.

Although Europe has been reluctant to embrace engineered crops, the first field trial of GE grapes took place in the northern Alsace region of France in 2005. This plant was engineered against fanleaf virus, which is transmitted by a small root-feeding nematode. Scientists inserted into rootstocks a coat-protein gene that stops replication of the virus (Bouquet *et al.*, 2003), while the scion—the portion grafted to the rootstock and which bears the fruit—is free of the foreign gene. Without a GE approach, growers must fight the fanleaf virus with a pesticide that has been banned in Germany, Switzerland and in some US states. Another viral target utilizing a GE approach was addressed with watermelon rootstocks engineered for resistance to cucumber green mottle mosaic virus (CGMMV) infection (Park *et al.*, 2005a).

Other examples outside the United States include relatively small acreage crops engineered with *Bt* genes. Indian, Canadian and French scientists collaborated to engineer cabbage with a fusion gene encoding two *Bacillus thuringiensis* crystal-endotoxin genes, which led to resistance to the diamondback moth (Anderson *et al.*, 2005). In 2000, scientists at the Centre de Coopération Internationale en Recherche Agronomique pour le Développement (CIRAD) in France planted in French Guiana GE coffee engineered with a *Bt* gene to test for protection against leaf-miner damage. In 2004 vandals removed the trial owing to fears that the engineered strains would enable richer farmers to put small farmers out of business (http://www.newscientist.com/channel/life/gm-food/). In 2005, scientists at the International Crops Research Institute for the Semi-Arid Tropics (ICRISAT) in India engineered and field-tested chickpea for resistance to legume pod-borer, *Helicoverpa armigera* (http://www.icrisat.org/gt-bt/GeneticEngineering.htm).

Improved Agronomic Performance

Such improvements are aimed primarily at the farmer, but could, given responsible usage, also have positive effects on the environment. One aspect of crop performance is yield. In 2001, transgenic rice plants expressing the maize proteins phosphoenolpyruvate carboxylase (PEPC) and pyruvate orthophosphate dikinase (PPDK) were found to exhibit higher photosynthetic capacity (up to 35%) compared to untransformed plants (Ku *et al.*, 2001). The simplicity of the change that resulted in the increased photosynthetic capacity in rice surprised many who had thought that such a dramatic increase in yield in a C3 plant relative to a C4 plant would require more complex modifications.

Another agronomic improvement involves the efficiency of utilization of nitrogen, resulting in less use of fertilizer and increased sustainability of farming practices. Japanese scientists introduced into the model organism, *Arabidopsis*, the plant-specific transcription factor, Dof1, to improve nitrogen assimilation (Yanagisawa *et al.*, 2004). Expressing

Dof1 induced up-regulation of genes encoding enzymes for carbon-skeleton production, a marked increase of amino acid content, and reduction in glucose level. Elementary analysis revealed that the nitrogen content increased by ~30%, and the engineered plants exhibited improved growth under low-nitrogen conditions.

Tolerance to Environmental Stresses

These traits aid the ability of plants to survive environmental stresses, like salinity, excessive and deficient water availability and high and low temperatures. Prior to developing a thorough molecular understanding of the regulatory mechanisms governing the plant's responses to these stresses, it appeared that strategies would have to focus independently on each individually. However, with the development of a detailed understanding of the mechanisms involved and their regulatory networks, it became possible to enable plants to deal with multiple environmental factors simultaneously with change in one gene.

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An example is the demonstration that the *CBF* genes, which are rapidly induced in response to low temperature, encode transcriptional activators that control the expression of genes containing C-repeat/dehydration-responsive regulatory elements in their promoters (Gilmour *et al.*, 2000). Constitutive expression of either *CBF1* or *CBF3* (also known as *DREB1b* and *DREB1a*, respectively) in engineered *Arabidopsis* was shown to induce the expression of target *COR* (cold-regulated) genes and to enhance freezing tolerance in nonacclimated plants.

Later, a homologue of the CBF/DREB1 proteins (CBF4) was shown to play an equivalent role during drought adaptation; CBF4 gene expression is upregulated by drought stress, but not by low temperatures (Haake *et al.*, 2002). Over-expression of CBF4 in engineered *Arabidopsis* resulted in activation of downstream genes involved in cold acclimation and drought adaptation and, as a result, engineered plants were more tolerant to freezing and drought stress. This approach was expanded to crop plants with the introduction of *DREB1A* into wheat for drought tolerance; field trials were conducted at the International Maize and Wheat Improvement Center (CIMMYT) in 2004 (http://www.cimmyt.org/english/webp/support/news/dreb.htm).

In another example, transgenic tomato plants over-expressing a vacuolar Na^+/H^+ antiport were able to grow, flower, and produce fruit in the presence of 200 m*M* sodium chloride, approximately 40% of sea-water concentration (Zhang and Blumwald, 2001). Although leaves accumulated high concentrations of sodium, the tomato fruit displayed very low sodium content. This confirmed that—contrary to prevailing thought—multiple traits do not have to be introduced by breeding to obtain salt-tolerance.

Increased Food and Feed Quality

The first demonstration of the use of GE to alter nutritional quality was the introduction of three genes into rice to create the much publicized Golden Rice, enriched in pro-vitamin A (Ye *et al.*, 2000). More recently one of the genes from daffodil, used in the original event, was replaced with a maize gene and the level of pro-vitamin A was thus increased 23-fold (Paine *et al.*, 2005) to a level likely to supply 50% of a child's recommended daily allowance in 72 g of dry rice.

Efforts have also been made to increase calcium levels three-fold in potato (Park *et al.*, 2005b). Levels of folate, an important vitamin for women of childbearing age, were increased in *Arabidopsis* to those in spinach by the introduction of a single bacterial gene (Hossain *et al.*, 2004). Indian scientists improved the nutritional quality of a staple in their diet, the potato, by introducing a nonallergenic protein from *Amaranthus*, thus increasing both total protein content and the amounts of essential amino acids (Chakraborty *et al.*, 2000). Recently, corn for animal feed was engineered for higher lysine content in order to reduce the need for lysine supplements (http://www.renessen.com/news/02.06.2006.eng.pdf).

Plants have been engineered to produce the heart-healthy omega-3 and omega-6 oils.

Plants have been engineered to produce the heart-healthy omega-3 and omega-6 oils, previously supplied mainly from fish sources (Qi *et al.*, 2004). Another area of intense interest relating to human consumption is engineering foods for decreased allergenicity, for example in rice (Nakamura and Matsuda, 1996) and wheat (Buchanan *et al.*, 1997).

Medical Applications

Many applications in this arena relate to the production of vaccines, both for animals and for humans. In one early application aimed at animal husbandry in Australia, clover was engineered to provide protection against shipping fever (Lee *et al.*, 2003). In 2006, the USDA approved a plant-based vaccine against Newcastle disease of chickens (http://www.checkbiotech.org/ blocks/dsp_document.cfm?doc_id=12154). Another approach to improved animal husbandry involved the actual engineering of a cow with higher levels of lysostaphin to lower the rate of mastitis infection by *Staphylococcus aureus* (Wall *et al.*, 2005).

Approaches utilizing GE plants to combat human disease include the development of a subunit vaccine against pneumonic and bubonic plague, which has been shown to be immunogenic in mice (Alvarez *et al.*, 2006), a potato-based vaccine for hepatitis B demonstrated to raise an immunological response in human test subjects (Thanavala *et al.*, 2005), a GE pollen vaccine that reduces allergy symptoms in sufferers (Niederberger *et al.*, 2004), and an edible rice-based vaccine targeted at allergic diseases like asthma, seasonal allergies and atopic dermatitis (Takaiwa 2006). The most successful commercial application of plant-produced protection was the synthesis in tobacco of a patient-specific vaccine for lymphoma (McCormick *et al.*, 1999); however, Large Scale Biology Inc., the commercial developer, was unable to identify investors for this approach, although proven successful in Phase-II clinical trials, and has since closed down.

Examples extend from the Enviropig™ to engineering plants to detect landmines.

Environmental Improvement

This category of applications includes examples that extend from the Enviropig™ to engineering plants to detect landmines. Researchers in Canada have developed a new breed of Yorkshire pig—the Enviropig™—that utilizes plant phosphorus more efficiently (Golovan *et al.*, 2001). Non-engineered pigs cannot use phytate, a form of phosphorus present in cereal grains. Accordingly, producers add to the diet supplemental phosphate or an enzyme, phytase, to meet phosphorus needs for optimal growth and development. The Enviropig™ has an enzyme in its saliva that allows it to degrade phytate and absorb the phosphate, thereby negating the need for supplemental phosphate or phytase, and as a result, phosphorus content of manure is reduced by as much as 60%.

Several efforts have been made to improve the ability of plants to remove heavy metals and other pollutants from the soil. One example is the engineering of the poplar tree to remediate soils contaminated with ionic and methylmercury (Rugh *et al.*, 1998). Another improves the ability of a member of the mustard family to take up selenium from the soil and transport it to the upper portions of the plant for harvest (Banuelos *et al.*, 2005).

The utilization of plants to produce alternative sources of fuels has recently become a focus of attention given the rise in energy prices in the United States. One approach involves the engineering of green algae to produce hydrogen gas, a renewable, clean fuel source (Melis and Happe, 2001). One of the most serious environmental pollutants is paper waste, particularly newspapers that, because of compaction, can remain in landfills for decades without decomposing. Recently, bacteria were engineered to help alleviate the global wastepaper glut (Fierobe *et al.*, 2005). One extremely dangerous environmental contaminant is the presence of landmines in specific areas; the problem is how to detect their presence without having them explode. University of Alberta and Duke University scientists are trying to develop plants that will indicate the location of landmines by changing color when their roots detect explosive compounds like TNT (http://cnews.canoe.ca/CNEWS/Science/2006/05/07/1568701-cp.html).

The Scotts Company has introduced a gene that slows the growth of grass, so-called Slo-Mow™, and reduces watering needs.

Other Applications

Countless amounts of energy and time are spent each year keeping the grass in home yards and on golf courses mowed. The Scotts Company has introduced a gene that slows the growth of grass, so-called Slo-Mow™, and reduces watering needs. Horticultural crops, like ornamental flowers, have also been a focus of engineering efforts. In Australia, Florigene Pty Ltd. succeeded in creating a number of new, vibrantly colored carnations, like Moonshadow™, some with delayed senescence (http://www.florigene.com.au/products/products.php?product_ name=Moonshadow). Long the "holy grail" of breeders, the blue rose was created by scientists in the Japanese company, Suntory (http://www.physorg.com/news3581.html). Breeders had attempted to make true blue roses for many years—prizes were even offered to anyone who could create them—but none were successful until they used genetic engineering technologies. First, RNAi was used to remove the gene encoding dihydroflavonol reductase (DFR) and then the delphinidin gene was introduced from pansy and the DFR gene from iris: *voilà*, a blue rose! Another aesthetic effort, this time at the pet store, was the creation of the GloFish™, accomplished by introducing a fluorescence gene into the aquarium zebra fish (http://www.glofish.com/). Under a black light, the fish appears to glow in the dark. An effort focused on eliminating the need for moths is the engineering of plants to produce silk-like proteins (Janaki Krishna, 2006).

A look at the lineup of future applications of genetic engineering in agriculture certainly makes it clear that, at this point, applications are not limited by the technology. Rather, progress is clouded by a number of factors that are outside the control of scientists.

Closing Thoughts

A look at the lineup of future applications of genetic engineering in agriculture certainly makes it clear that, at this point, applications are not limited by the technology. Rather, progress is clouded by a number of factors that are outside the control of scientists, particularly academic scientists. Although public-sector scientists have played a role in variety development of plants and animals in the past—using classical breeding and mutational approaches—their ability to participate effectively in this arena is limited by issues like very high regulatory costs and limited access to key technologies because of intellectual-property protection. These factors, in addition to consumer-acceptance issues, will determine the future applications of genetic engineering of crops and animals. Will such approaches be used to address the specific problems of agriculture in the United States? Even if this is not the case in the near term, it is likely that these technologies will play an important role in other countries, for example China, where these issues are not likely to be key factors in their utilization.

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Dr. Lemaux's research group focuses on both basic and practical questions relating to the genetic engineering of cereal crops. Her group has worked on projects aimed at reducing allergenicity in wheat and increasing digestibility of sorghum, the latter project to improve human nutrition in developing countries. She devotes a significant portion of her time to educational outreach aimed at public understanding of agricultural practices and food production and the impact of new technologies on food and agriculture. These efforts have increased owing to efforts in California counties to pass anti- and pro-GMO ordinances and resolutions. She spearheaded the development of an award-winning educational website (http://ucbiotech.org) that provides science-based information on biotechnology.

Research to Market/Public Good: Economic Perspectives

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This presentation provides an overview of the NABC-18 theme, *Economic Development Through New Products, Partnerships and Workforce Development*, from an economic perspective. With special reference to agricultural (bio)technology, specifically it outlines methods used for science/technology transfer to markets and public good, provides public and private sector examples of venture capital for early commercialization of agricultural science and technology, and describes issues and recommendations for effective technology transfer to market including public good.

The views expressed in this presentation are mine based on experience in academia, large and start-up industry, and government including as a board member of a government venture-capital corporation [Alternative Agricultural Research and Commercialization (AARC) Corporation] and as an advisory board member of a private venture-capital corporation (Foragen Technologies, Inc.). As president of NABC and a last-minute substitute speaker for Roger Wyse of Burrill & Company, a life sciences merchant bank, I emphasize that the views expressed here are not necessarily those of NABC.

Economic Methods Used for Technology Transfer

Licensing

Much of the research by not-for-profit institutions, *e.g.* universities, government laboratories, research institutes, is to generate knowledge, but such research also results in innovation with potential for commercial products and processes and public good. The majority of not-for-profit research is in this area, with most funding from the public sector. Based on the source of the funding and the mission of the not-for-profit institutions, it is their obligation to provide benefits to the public. In the past, plant breeding utilized

Maximization of public good should be the objective of technology transfer, not maximization of revenue.

public varieties as the transfer vehicle, but such transfer nowadays usually is done by licensing. In 2004, the top ten US universities (based on $$ of sponsored research) had $10 billion of sponsored research and gross licensing revenues of less than $300 million, or less than 3% of the sponsored research, ranging from 0.4% to 7% (Laurence, 2006). Licensing revenue makes a very small contribution to not-for-profit research, is highly variable and is not very predictable. The historic examples are the University of Wisconsin vitamin-D irradiation of milk and the rodent poison and human blood thinner warfarin, and more recently the Stanford/University of California fundamental process for making transgenics. Most not-for-profit institutions have established technology-transfer offices. In *Issues and Recommendations* below, I will recommend that maximization of public good should be the objective of technology transfer, not maximization of revenue. This view will be amplified by Mark Crowell in his presentation on *Knowledge Transfer and Economic Development: The Role of the Engaged University in the Twenty-First Century*.

Research Contracts

For-profit corporations provide contract support for not-for-profit research with the objective of generation of technology/know-how for improvement of existing products or processes or development of new products and processes. Research contracts may represent 5% to 20% of research support for more-applied not-for-profit research, such as agriculture and biotechnology. In most cases, the funder will obtain exclusive commercial rights to the technology, including patents for a license fee that is probably predetermined. It is preferable that the not-for-profit entity, not the funding industry, be the owner of the intellectual property, with licensing of rights to the industry. Research rights should be maintained by the not-for-profit. The government uses Cooperative Research and Development Agreements (CRADAs) and these will be discussed by Richard Brenner in his presentation, *Technology Transfer in ARS: Implications of Federal/Private Sector and Federal/University Partnerships to Commercialization Strategies*.

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Various Government Grants to Facilitate Early Development and Commercialization

These include Small Business Innovation Research (SBIR) grants to facilitate small-company product and process development, such as feasibility studies and business-plan development. William Goldner will describe this program (*The USDA Small Business Innovative Research Program: Vision, Challenge, and Opportunity*). The Defence Advanced Research Projects Agency (DARPA) has a similar grants program. These programs are important for cash-strapped new companies since they do not require repayment, and Michael Adang (*From the Bench to a Product: Academics and Entrepreneurship*) will provide a real example. The Department of Energy (DOE) has used major grants to drive biobased industrial products with major industry often the lead organization with subcontracts to other industries and not-for-profits; a recent example is the multifold reduction in cost of cellulase enzymes for use with cellulosics for ethanol production.

Technology Parks

Technology parks have been shown to be useful in bridging the so-called "valley of death," the gap between laboratory research and resultant potential technology and conversion to a commercial endeavor. Such parks enable direct interaction between the scientific innovator and the company seeking to develop and commercialize the product or process. Presentations by Allen Dines (*From Equines to Economic Development: The Story of University Research Park*) will describe the highly successful three-pronged approach in Wisconsin with over 80 years of highly successful experience and by Ashley O'Sullivan (*From Tools to Products and Processes: The Evolution of Saskatchewan's Ag Biotech Cluster*) who will describe what is probably the most successful agriculturally focussed technology park with about 20 years experience. Our visit to the Cornell Agricultural and Food Technology Park (CAFTP) in Geneva, NY, will provide an opportunity to explore issues facing a "just born" technology park.

International Examples

Other presentations at this meeting will provide examples from other countries of the transfer of research to market and the public. Zhangliang Chen (*Innovation: The Chinese Experience*) will describe the connected relationship between the university and the establishment and operation of major businesses, with substantial economic benefit to the university; such a relationship probably would not be acceptable in the United States. Wim Jongen (*Food for Innovation*) will describe the Wageningen Business Generator, which has similarities to Canadian and US research parks. Other examples include India, Brazil and Germany. This broad experience-base, and their respective strengths and weaknesses should guide future activities in this emerging area of technology transfer. A reality check is provided by Richard Broglie (*Translating Discovery Research into Commercial Products*), presenting the perspective of a major agri-food-chemical company.

Various Forms of Investment in New Companies

Equity investment is more useful for new companies than loans; new companies are almost always strapped for cash and, therefore, interest payments consume money that is needed to invest in the business. I have had several years' personal experience with a government-funded venture-capital corporation and with a privately funded venture-capital corporation. Both were investors in early-stage commercialization.

The AARC Corporation was authorized by the 1990 Farm Bill as a wholly owned government corporation within USDA. Its mission was to commercialize industrial uses of ag and forestry materials to create, in the long term, new markets and reduce subsidies for agriculture. AARC had many strengths, including a mainly non-bureaucrat board with initially over 50% having been presidents or vice-presidents of for-profit corporations. It was operated as a business, making investments in the most promising companies, with little emphasis on geographic location and with ability to make equity investments, which was unique to government where grants and low-interest loans were the norm, requiring matches of at least 1:1 of non-AARC to AARC investments, and in-depth due diligence with external expert review of proposals and on-site reviews by staff and at least one board member, prior to investment, with subsequent on-site annual or more-frequent monitoring. The weaknesses were the inexperience of government with venture-capital and the venture-capital approach where projected return is directly variant with risk, impact of shifting political "winds" on funding, ability only to invest if private funds were not available (in other words, the source of last resort) and, finally, the inability to move the "AARC activity" to a non-government-funded corporation with expanded resources for continuing and expanded equity investments in biobased products and processes. Equity funding for agriculture-related new companies is minimal; an exception may be occurring with the current exploding interest of Wall Street in cornstarch-ethanol investment where the possibility of too much/too fast is a real concern. There is a major continuing need for government to play a role with early venture capital, but it would need to avoid the above weaknesses. Up-front endowment-type government funding may work, as with the very successful Canadian Foundation for Innovation in the late 1990s.

Examples of products/processes funded by AARC [*e.g.* AARC Corporation (1997)] included milkweed fiber for hypoallergenic comforters and pillows, D-ribose for cardiovascular function, biodegradable plant oils for engine lubrication, capsaicins from hot peppers to keep mammals out of avian food, *e.g.* squirrel-free birdseed, and gasification of biomass and its high-yield biological conversion to ethanol.

Foragen Technologies, Inc., is a Canada-based venture-capital company founded in the late 1990s. Funding came from the private sector. It funded very early commercialization as mainly not-for-profit innovations were evaluated and developed as new businesses. A number of promising investments were made. However, a second round of investment in Foragen Technologies by the private sector did not occur, probably based on the perception that agriculture is not an attractive area for venture capital. This is in contrast to the abundant venture capital for human-health-related innovations.

Issues and Recommendations

Several issues and recommendations will be noted, with the hope of stimulating discussion and improving efficacy of research to market/public good transfers.

Maximize Public Good from Public-Sector Research

Licensing income is small. Technology transfer should maximize public good not maximize licensing income[1]. Evaluations by and of technology-transfer offices should use the public-good metric, not the income metric.

Intellectual Property

Seeking protection of IP should be based on a realistic assessment of potential. Business-experienced alumni can be helpful in providing guidance on decision-making regarding filing of patents. When it is decided not to file a patent, the right to file could be assigned to the inventors. The most promising patents should be filed broadly and patent estates built around them. Failure to find business interest in a patent within a reasonable time should lead to timely abandonment so as to avoid continuing maintenance costs. Although universities file and are awarded large numbers of patents (Rovner, 2006), only a few result in significant products and/or processes

Venture Capital

Venture capital for agricultural innovations, other than human-health uses—is inadequate. A method is needed for significant government funding of this area without the variability of political impact. Up-front endowment funding may be such a method.

The path to market is the single most decisive factor for success of a new company.

Path to Market

My experience is that the path to market is the single most decisive factor for success of a new company, more so than any other factor, such as entrepreneurial leadership, funding or technology.

[1]Robert E. Armstrong, senior research fellow at the National Defence University, suggests that the Apache "open source" community in the computer-software industry, as described by Tom Friedman in *The World is Flat* (New York: Farrar, Straus and Giroux, 2005), illustrates maximizing the public good while enabling economic return to industry. The Apache "open source" community is a collaboration of computer scientists self-organized to develop programming to run Web services. In the Apache collaborative community you could use community technology, but were required to make any improvements available to the community. In addition, industry could build a patented commercial product utilizing the "Apache code," but were required to include a copyright citation in their patent. Substantial revenue has been generated by IBM utilizing this approach in the Web-server business, while the base technology is broadly available. Plant breeding public research with seed-company development of commercial products is an earlier example. The recent collaboration of several not-for-profit research institutions to retain research uses and applications for developing-country uses of biotechnology patents is another example.

Deal Yield

A large number of deals need to be assessed to find the few that are worthy of investment. The yield is in the range of one out of every twenty-five to fifty considered. "Back-of-the-envelope" calculations eliminate many deals.

Business CEOs

Scientist innovators usually are not successful as business CEOs. A rule of one venture-capital manager was "Shoot the inventor." There are exceptions, but business CEOs need to focus, focus, focus on the business objectives, whereas scientists' success usually results from broad curiosity.

Difficult Areas for New Businesses

Some examples where failure is common (based on my experience) are construction and building materials that require a huge scale of production, *e.g.* the 100 million ft^2 straw-based particleboard plant in Manitoba, most recently operated by Dow, was closed in early 2006. Another difficult area is new crops. Most are long-term efforts and need the staying power of the public sector. Canola, as described by Keith Downey (*Rapeseed to Canola: Rags to Riches*), is an example of relatively rapid development of a new crop, but there are many other oil (and other) crops for which development has been tortuous. Another area with a low success rate is microbial pesticides. While plant-based biopesticide products have been quite successful, microbial pesticide-based companies have a history of failure. Technology platforms are difficult in defining the business path to market.

There are other issues that I am sure will be discussed at the breakout sessions. I hope the above will help stimulate your discussions. Improving the transfer of research to the market/public good has major opportunities for improvement

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RALPH W.F. HARDY—a leader in science and management in the for-profit and not-for-profit sectors of the agricultural life sciences—has contributed significantly in the fields of biochemistry, physiology, and agronomy.

Dr. Hardy is president and co-founder of NABC. Previously, he was president of BioTechnica International and president and CEO of the Boyce Thompson Institute for Plant Research, Inc. He was with DuPont for 21 years, where he led the research-driven diversification into pharmaceuticals, agricultural products, and biobased products. He is a leading spokesperson on the biobased economy and its potential for public good.

Road Bumps and Pitfalls for Agricultural Biotechnology

Deborah Delmer
Rockefeller Foundation
New York, NY

The problems for biotechnology vary according to who you are—a large company that deals with important crops and developed-country farmers, a small private company, a public sector entity, university, national agricultural system or a CGIAR institution—which I will come back to. As far as public/private partnerships are concerned, the Rockefeller Foundation has seen success in collaboration with the Gates Foundation in creating such partnerships to tackle medical problems, such as AIDS, TB and malaria, but so far we have not had a single similar success for agriculture. Where you are is important also—the northern markets or Australia is one story and genetically engineered (GE) crops are really taking off in some dynamic developing countries benefiting rich and poor farmers. In Africa, where we spend a lot of our time, the problems are different again.

I am not in the private sector and can only guess as to what is worrying big industry at this point, and whether the Europeans will ever sort it out is an ongoing question that I will not dwell upon; however, there are signs of progress, with GE crops now planted in a few countries within the European Union.

The Next Generation

Some large companies are getting close to marketing the next generation of traits, beyond *Bt* and herbicide tolerance. The big questions will be:

- How do you capture value for quality traits?
- Will they require market segregation?
- Will genes for value-added traits be stacked with "conventional" insect resistance and herbicide tolerance?

Clearly, stacking is "in," to the benefit of companies like Monsanto and companies like Pioneer need to form partnerships to obtain enough traits to stack effectively and be competitive. From the point of view of those of us who support projects on Golden Rice and other nutritional improvements, it is hoped that the private sector will lead the way on stacking of traits and get the regulatory systems to accept them, because when you alter nutrition it is probable that little will be achieved by changing one trait at a time.

Liability issues are of particular concern to smaller companies, with the effect of delaying the release of new products. Multinational companies have invested significant time in Latin America in particular and India in discussions on protection of intellectual property (IP). Interesting models are emerging from Argentina and Brazil in conjunction with Monsanto; where patents have not been filed it may be possible to collect revenue from the end-user.

India is causing concern in demanding pricing structures, resulting in lowering of technology fees. On the positive side, large US companies see India—and China—as possible new markets including for GE products, which may have particular utility in the developing world. For the longer term, there is worry over competition from local producers of GE foods.

The cultures of the public and the private sectors are very different.

The large private-sector companies face many challenges in dealing with issues specific to the developing world and Africa in particular. Clearly, these companies would like to build long-term markets for maize and cotton and are trying to balance humanitarian interests with commercial interests. We are trying to facilitate public/private partnership discussions, but the issues are complex and the cultures of the public and the private sectors are very different. It's a huge challenge.

Where are the public sector and the small private sector in terms of bringing promising new GE products to the market-place? Where are the products listed by Peggy Lemaux[1]? Very few have come to market. Salient also is the issue of moving innovations efficiently downstream from universities; I agree with Ralph Hardy[2] that many scientists in public-sector research lack business skills and know little about developing products that would have market-appeal for the common good.

Freedom to operate is a perpetual problem as is the high cost of regulation, particularly so for smaller-market specialty crops that university and small private companies are interested in.

Public Perception

It is difficult to judge the degree to which negative public perception of GE foods remains a significant issue. It is noteworthy that very strong research programs on developing GE crops are in progress in China, India and Brazil. On one hand, EMBRAPA in Brazil and India have a number of strong research institutes, but, on the other hand, there is a dearth of experience in bringing GE crops to market, at least by the public sector. *Bt* rice may be approved for commercial production soon in China and India and it is

[1]Pages 31–42
[2]Pages 43–50

hoped that *Bt* eggplant—an example of a new GE crop resulting from a public/private (Mahyco, India) partnership—will be available to farmers in India, Bangladesh and the Philippines late in 2006.

Almost everything we talk about now is in terms of building dynamic national economies rather than stabilizing subsistence agriculture as the means of achieving sustainability.

The public sector has to strike the right balance between commercial and noncommercial delivery systems. It is the issue of public good and even at the Rockefeller Foundation, which has a history in dealing with issues such as the Green Revolution as well as noncommercial aspects of agriculture, almost everything we talk about now is in terms of building dynamic national economies rather than stabilizing subsistence agriculture as the means of achieving sustainability. We are no longer talking in terms of just giving away GE crops. In any case, liability concerns and lack of adequate distribution systems preclude giving them away. Finding commercial models and developing seed systems beyond maize will be a challenge certainly in the poorer developing countries but may be a struggle also for minor crops in dynamic countries in the developing world.

As far as regulatory aspects are concerned, many countries started by following the US model with a conservative bent, placing restrictions where there was room for doubt. With experience, a risk *vs.* benefit philosophy has become more prevalent with the realization that if the approach is too strict no new products would see commercialization.

In the least developed countries where the Rockefeller Foundation does a lot of funding, particularly in Africa, we have to consider public perception and the NGOs. However, I am becoming more optimistic in this regard. I think that people are tiring of this debate and that there is opportunity for progress. A huge problem is weak research capacity in these small least-developed countries; seldom should you expect to fund projects for development in those countries in isolation. And it's a challenge to find good partners in universities willing to train postdoctorals and build long-term research capacity in those countries. Finding the models for training and partners for projects is a challenge.

In terms of defining the relationship with the private sector, we've seen some public sector projects that are trying to repeat what large private sector companies are doing. For example, developing *Bt* maize for Africa doesn't make sense for the public sector when Monsanto has a perfectly good product. We have to be strategic and examine what the private sector will not tackle.

Many donors who are extremely timid about funding GE projects in the developing world, with the notable exception of the US Agency for International Development, The Rockefeller Foundation and, to some extent, the McKnight Foundation. For this reason, the CGIAR centers are not at the cutting edge of biotech research. None of the

European donors are interested in funding this work. However, the good news is the Gates Foundation is quietly tip-toeing in and it is to be hoped that they will fund successful projects that will encourage them to remain involved, which could significantly change the dynamics.

My biggest push in Africa is to encourage countries to let their scientists enter partnerships and develop new crops themselves that are locally appropriate.

Intellectual Property

These issues may be simple or complicated. In Malawi, for example, developers of GE crops wouldn't need to worry about patents. A developed-country counterpart interested in partnering with scientists in Malawi might be able to manage the IP, depending on how the project is structured. I was happy to see NABC's guidelines for field-research trials with GE crops (NABC, 2006). My biggest push in Africa is not to convince countries to release GE crops to farmers. It is to encourage countries to let their scientists enter partnerships and develop new crops themselves that are locally appropriate. In order to participate in that development they have to be able to do simple research trials on site, in their own countries. In no other way will this move forward. Africans, Indians, Chinese, all want ownership of these crops as they develop them and if those trials cannot be done, it will never happen. Simple research trials and understanding of how to do them safely and responsibly are required, at low cost and with minimal effort. It should not take 2 or 3 years to obtain a permit for a simple trial, as it does now in Kenya.

Event-specific regulation is a real challenge. If you consider how difficult they are to breed and if we follow the US model of event-specific regulations, then we have a real problem in moving traits to locally adapted varieties of cassava and banana. We need a new model.

And we need regional harmonization in Africa. Although that continent will not be the breadbasket of Europe any time in the near future, there are tremendous opportunities for regional markets in Africa with the growing urban populations. Regional harmonization of biosafety regimes, quarantine restrictions, seed certification and so on will facilitate access to new regional markets.

On the sharing of IP, the Public Intellectual Property Resource for Agriculture (PIPRA) has the objective of assisting public-sector institutions in garnering IP and strengthening management skills. PIPRA now encompasses thirty-seven institutions in six countries. They will meet in the spring of 2007 to explore bringing Europe into the fold, and more countries. They have got an IP database online where they list the licensing for all of their technologies. For anyone interested in obtaining vectors with freedom to operate, PIPRA is now constructing them using its own public-sector IP. We hope that it will become available in a year or two.

The AATF is a fledgling organization learning how to broker technology transfer in Africa.

The African Agricultural Technology Foundation is a fledgling organization learning how to broker technology transfer in Africa. Some very smart Africans running it have already had some success. Cambia Biosys has devised another model for possible open-source licensing.

Good News

There is some good news and some bad news. The good news is the rapidly increasing global acreage planted to GE crops. And it's noteworthy that GE crops are now being planted in five EU countries. Certainly poor farmers are beginning to benefit along with large farmers in some of the dynamic developing countries, as indicated in published data from South Africa, China, India, Brazil and Argentina. Interestingly, in Africa it is happening in Burkina Faso; Monsanto is partnering tactfully with local scientists there in a series of trials of *Bt* cotton. They are moving the Bollgard-2® trait into locally adapted varieties with very promising results. Working with their most advanced trait is smart management. This approach has changed the mindset of West African farmers to whom we have spoken. Suddenly they are saying, "Hey, if they have it in Burkina Faso then we must have it too." And that is how this will work in Africa: the people have to see it. And even though Monsanto will never get rich from Burkina Faso, it's the kind of thing we need to see happen.

Not So Good

On the other hand, no GE food crop has been released for commercial use in China or India and it is unclear when this will happen, despite its expectation in recent years. In all of Africa, South Africa is the only country where GE crops are growing, but we are seeing movement in East and West Africa: a lot more interest and a lot less fear. Illegal sale of GE seeds has been a problem, *e.g.* in India with *Bt* cotton and in Brazil with Roundup Ready® soy. It may be less of a problem with the next generation of GE traits, as companies learn how to handle this.

An article out of Pretoria, in South Africa reported that poor farmers were doing well in the early days of *Bt* cotton when only one gin was accessible. The owners of the gin loaned the farmers the money to pay the high cost of the seed, and at the end of the season the loan was returned in kind when the farmers brought their cotton to the gin. Then, a second gin opened and the farmers said, "We'll take the loan and the seed from the first gin but we'll sell our cotton to the second gin." Well, guess what, micro-credit is no longer available for these farmers. These are how institutional problems can create difficulties. We are still trying to get it right between the public and the private sectors.

The need to harmonize in West, East and South Africa is becoming clear; individual countries are too poor to do this on their own.

In Summary

We need many skills to strengthen IP regimes. Similarly on regulatory issues, the Specialty Crops Initiative promises to provide cheaper field trials. The need to harmonize in West, East and South Africa is becoming clear; individual countries are too poor to do this on their own. For a long time, 10% of the people have said this is great stuff and another 10% have expressed distaste. In the middle is a vast disengaged majority who really don't care, including many farmers in the developing world. I think that people are just tired of it. Let's get on with it. Let's just move on. It may not be an overflowing cup, but I'd say it's more than half-full.

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Deborah Delmer received her BA degree with honors in bacteriology from Indiana University in 1963 and her PhD in cell biology from the University of California San Diego in 1968. She has held faculty positions at Michigan State University, The Hebrew University of Jerusalem, and the University of California Davis where she was chair of the Section of Plant Biology.

With colleagues at Calgene, Inc., Dr. Delmer's group was the first to identify plant homologs of bacterial genes that encode the catalytic subunit of cellulose synthase and she was recognized for her work on cellulose synthesis by the American Chemical Society with their 2004 Anselme Payen Award. She also served as president of the American Society of Plant Biologists and is a member of the US National Academy of Sciences.

Since 2002, Delmer has served as associate director for Food Security for the Rockefeller Foundation where she is charged with grant-making and policy relating to biotechnology's role in advancing improvements in crops for the developing world. She is also involved in efforts by the Foundation to address problems of intellectual property rights and biosafety that are important for development of genetically modified crops important to the developing world.

Past Successes, Future Prospects and Hurdles

Session I Q&A

Moderator: Robert Seem
Cornell University/New York State Agriculture Experiment Station
Geneva, NY

> *US agriculture is going to move beyond food and fiber into other technologies, and that's where the future of agriculture really lies, the most promising part.*

Bob Seem: The floor is open. Questions?

Audience member: For Alan Wood—did the USDA task force consider obesity?

Alan Wood (Boyce Thompson Institute): Obesity was mentioned as a problem that needs to be dealt with, but it was not one of the very specific things that we dealt with. It had to do with research in areas of health that we need more of in the agricultural sector. The USDA already has programs dealing with this. What we were looking at was something beyond current programs in agriculture. We felt that many issues are not being addressed. We were looking forward to the future in agriculture. And the future in agriculture is that we need to come up with new ways of doing business. We need to come up with new products and new technologies and understand where the competition lies. When we go to the grocery store, my wife always looks to see where things come from. Thirty years ago you didn't need to look at a label to know where something came from. The feeling on that committee was that US agriculture is going to move beyond food and fiber into other technologies, and that's where the future of agriculture really lies, the most promising part.

Ralph Hardy (National Agricultural Biotechnology Council): Let me add a comment. In 2002 the NABC meeting was held in Minneapolis and the focus was *Foods for Health*.[1] We made a start at looking at this area, the connect between agriculture, food, medicine

[1]Eaglesham A Carlson C Hardy RWF (2002) NABC Report 14 on Foods For Health: Integrating Agriculture, Medicine and Food for Future Health, 340 pp. Ithaca, NY: National Agricultural Biotechnology Council.

and health. There have been other attempts to connect these, but they haven't "gelled" to the degree they should. We are going to need to maximize the food-input nutritional side to contain healthcare costs, which are soaring. At NABC, we see this as a focal point; a document is planned to help bring visibility to, and generate traction for, this important area. Efforts are ongoing in Canada in the same vein, because budgets are going to increasingly be cramped, be limited, by increasing healthcare costs if we don't deal with obesity, cardiovascular disease, diabetes, some cancers, in all of which, agriculture—through input—has a significant role to play.

Keith Downey (Agriculture Canada): Something that concerns me is the very high cost of regulation, yet we talk about the small crops that we are going to improve. If those small crops are to be grown in multiple countries then you have to go through that regulation time after time after time, and I see that as a major stumbling block for biotechnology exploitation in the near and long terms.

Debbie Delmer (Rockefeller Foundation): With regional harmonization discussions in Africa, people are beginning to realize that small countries just can't afford the delays and the costs. Part of the regional process would be accepting regulatory information that comes from other countries. Also very important for public-sector efforts is having the private sector share their information whenever they can. As I said, the more people deal with this the more sensible they become.

As far as regulatory costs are concerned, there's no way the academic sector is going to play a role.

Peggy Lemaux (University of California at Berkeley): In some ways California is a developing country in that we deal in so many smaller food crops. We grow 300 different crops. Of course public perception is also an issue, but as far as regulatory costs are concerned, there's no way the academic sector is going to play a role. I wish it were otherwise, but I don't see a way. We have worked on developing hypo-allergenic wheat—but go to your dean and say that $3 million will do it. There's no way!

There is an issue regarding something that is eaten five times a day. How often are eggplant, papaya or artichokes, for example, eaten? I hope that we can get around that or the public sector will not play a direct role, and I think we should.

Peter Welters (Phytowelt, Germany): Deborah when you were talking about PIPRA[2], you said that the Europeans are not in there and you want to get them in. Does that mean that the transgenic vectors you are constructing have no freedom to operate in Europe?

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[2]Public Intellectual Property Resource for Agriculture.

Delmer: I'm not sure if PIPRA has members in Europe. There have been enquiries about it from institutions in Europe. Discussions have been held with universities and public-sector institutions, so we will devote September 2006 Bellagio Conference to PIPRA. They may not join PIPRA, but they may use it as a model to form their own alliances or a consortium. PIPRA has a couple of Latin American members and one African, and is beginning to pick up some of the CGIAR[3] centers. The Europeans will have to decide whether their IP systems are so different that it would not work to put them together. It's at the discussion stage.

Yongfei Zhang (Cornell University): This is a question for Peggy. I'm interested to know what are the major concerns of the public and potato industry regarding GM potatoes? Do you see any signs of change for the near future?

Lemaux: It's difficult to know. It requires major players coming forward. A few have come forward and said, "We see a benefit and we're going to put them out there," then failed to follow through. When I first took this job in 1991 I said that the way to win people over is to get McDonald's to use genetically engineered potatoes as French fries. The little kids say, "Mommy we want fries," and she says, "No honey, it's GMO." Then they cry and she gets them the French fries and they're okay and they have ketchup with genetically engineered tomatoes and they are still okay. But the food companies were scared. At some point it's going to work out, but when it's going to happen, I don't know. And I don't know the potato industry like I know the cereal industry. Maybe someone else does.

Dalia Abbas (University of Minnesota): This question is for Ralph. How you would construct an economic model that can assess the cost and benefits of agricultural biotechnology? You mentioned it's an important phase. I'm trying to visualize inputs and outputs and I'm trying to find where are the barriers and what are the main inputs there?

Ralph Hardy (National Agricultural Biotechnology Council): Well most commercial products in the United States are based on traditional costs, not life-cycle costs. And so, what models that we have experience with have worked? What are their limitations? Where might we improve them? I also said that we need to refocus to maximize public good, not necessarily to maximize economic return to the inventing institute or to the inventor. The public paid for the research, therefore the public should benefit most from the research—that should be the priority.

We had a presentation a couple of years ago from the inventor of virus-resistant papaya[4] and that was an example that was totally done within the public sector. Surprisingly, the cost through the regulatory hoops was significantly less than a million dollars. That's one of the models that I'm surprised we haven't used more. What relevance does the papaya

[3]Consultative Group on International Agricultural Research.

[4]Dennis Gonsalvez (2003) The papaya story: A special case or a generic approach? In: Eaglesham A *et al.* (eds.) NABC Report 15, Biotechnology: Science and Society at a Crossroad, 223–230. Ithaca, NY: National Agricultural Biotechnology Council.

story have? It is a small crop, with the research and commercialization within the public sector. They were able to get the genetic materials licensed in Hawaii. Why isn't that story relevant to some of these other areas?

Lemaux: Flax is another, done in Canada within the public sector. I've talked to both of those people—Dennis Gonsalves and Alan McHughen—and they believe it is possible. Things have changed. They weren't on the radar screen at the time. They talked to government officials and it went a lot easier. There might be a few other instances where they could get something like that through, but I don't know if it's going to be a generalized model.

Delmer: I think Dennis Gonsalvez would say that they weren't much on the radar screen at that time. They went to Monsanto and said, "Hey, give us these rights, come on," and the IP negotiations weren't difficult. Regulatory restrictions were minimal for what they needed to do. Now Dennis wants approval to sell in Japan and he's had to jump through a lot more hoops. But he thinks—or thought—that he will be able to do it; I don't know where it stands now. Maybe Dr. Vijayaraghavan can say something about Indonesia and the Philippines—but the papaya is on the move there. They are optimistic for the Philippines where field trials are expected soon. As I said, there is a new wave. Maybe we've been through the worst.

Ajay Garg (Cornell University): Thomas Friedman was on CSPAN being interviewed on his book *The World is Flat*. Since the world is flat I am wondering if there is opportunity for transparency in this genetically modified business. Is it possible to bring together the leaders of agbiotech to achieve transparency in evaluating transgenic material? Can eminent scientists, irrespective of their countries, come together to critically evaluate the technology?

Wood: One of Friedman's points is that this type of thing is occurring because the world has gotten so small through communications. He doesn't deal specifically with agriculture, but it's easy to extrapolate from the examples that he gives for industry and academic institutions where exchange of information and resources has just gone wild in such a way that barriers between countries are being broken down. Within industries, one of which of course is the agriculture industry, in the past, we didn't think much about what was going on half way around the world. In contrast, in today's agriculture a smart farmer worries about what's going on around the world, and he has access to the information.

Delmer: One of the activities of the Gates Foundation is in putting money into five of the national academies of science in Africa, to try to strengthen the role of science in policy decisions in Africa in much the same way that our National Academies of Science serve as advisors to the government on many issues. That may be close to what you are suggesting. If the academies could be strengthened and their voices heard, it could well be of some help, particularly in these policy decisions.

Bt cotton moved into India and Roundup Ready soybeans moved into South America because the world is flat.

Tony Shelton (Cornell University): It's interesting that you mention *The World is Flat*. *Bt* cotton moved into India and Roundup Ready soybeans moved into South America because the world is flat. "Stealth" seeds, moved from one country to another, actually forced the regulatory agencies in those countries to address what at least the farmers wanted there. So, the world *is* flat and it's changing things in ways that cannot always be predicted.

Past Successes, Future Prospects and Hurdles

Session II

Rapeseed to Canola: Rags to Riches

R. Keith Downey
Agriculture and Agri-Food Canada Research Centre
Saskatoon, SK

This story began some 65 years ago, during World War II. It is a story of successful genetic manipulation of an introduced crop by a small, self-motivated team of chemists, plant breeders and animal nutritionists. As a result of their efforts, the crop now rivals wheat as Canada's most valuable agricultural commodity and is the world's third most important source of edible vegetable oil (Table 1).

A story of successful genetic manipulation of an introduced crop by a small, self-motivated team of chemists, plant breeders and animal nutritionists.

Table 1. World edible vegetable oil production by crop (millions of tonnes).

Oil crop	Production year 83–84	93–94	02–03	% growth in 20 years
Soybean	13	18	31	142
Palm	6.3	13	28	343
Canola/Rape	4.9	9.2	12	151
Sunflower	5.4	7.2	8.6	59
Cotton	3.0	3.4	3.9	30
Peanut	2.9	3.6	4.4	52
Other*	4.7	6.4	9.5	103
Total	40	61	98	144

*Olive, coconut, palm kernel, corn, *etc*.

Critical Need for Lubricants

During World War II, all trains and ships were steam-powdered and rapeseed-oil lubrication was essential to keep them running. When metal surfaces are washed with steam or water, rape oil clings better than any other natural or synthetic lubricant. When supplies of the oil from Europe and Asia were cut off, Canada was asked to attempt to grow the crop. Experimental plantings showed that with minor adjustments to seeding and harvesting equipment the crop could be grown in the cooler, moister regions of the Canadian prairies.

Two species of the crop, *Brassica napus* and *B. rapa* were marketed as a single commodity. The black, brown or yellow seed is small and round and when crushed yields 40 to 46% oil and a nutritionally well balanced, high protein (36–37%) meal. The seed looks like those of turnip, mustard or cabbage, to which they are closely related.

Commercial production began in 1943 with a government-guaranteed price of $.06/lb and production expanded from a few acres in 1943 to 79,000 by 1948 when the price support was withdrawn and steam power was displaced by diesel. The crop almost disappeared in 1950 until an edible oil market was established in Japan where rapeseed oil was preferred for deep frying (tempura). After the war, the Japanese no longer had the farm labor to transplant rapeseed into the rice stubble to obtain two crops per year. Thus, the Canadian crop was saved while providing time to develop a domestic market.

Edible Oil from Rapeseed?

From the beginning it was recognized by scientists that rapeseed could be an important domestic source of edible oil. At the time, Canada was importing 90% of its edible oil needs. Indeed some local companies began to market the liquid oil in the early 1950s. However, the fatty acid composition of rapeseed oil differed from those of other edible oils in having a substantial quantity of the long-chain monoenoic fatty acids, eicosenoic and erucic (Table 2). This difference sparked the interest of nutritionists. Initially they reported that rats fed high levels of rapeseed oil performed poorly under stress and had enlarged adrenals. To counter these reports, it was pointed out that Asian peoples had consumed rapeseed oil for centuries with no ill effects. Thus, the domestic market was allowed to grow.

Table 2. Percent fatty acid composition of Canadian vegetable oils.

Fatty Acid	Symbol	Rapeseed			Soybean	Sunflower
		napus	*rapa*	canola		
Palmitic	C16:0	4.0	4.9	4.7	12	7.2
Stearic	C18:0	1.5	1.6	1.8	3.9	4.1
Oleic	C18:1	17	33	63	25	16
Linoleic	C18:2	13	20	20	52	73
Linolenic	C18:3	9.0	7.6	8.6	8.0	0.0
Eicosenoic	C20:1	15	9.9	1.9	0.0	0.0
Erucic	C22:1	41	23	0.0	0.0	0.0

Decreased Erucic Acid

Because of the nutritional concerns, chemists and breeders turned their attention to developing techniques to search for and develop germplasm with little or no-long chain fatty acids. At the time it required 2 lb of seed and a technician 1 week just to determine the fatty acid chain lengths of an oil. Gas chromatography (GC) was being developed, and home-made instruments were built to screen the world's rapeseed germplasm. With no computers or integrators, each GC peak had to be triangulated and measured by hand. We were fortunate to identify a poorly adapted European forage variety with a much-reduced level of erucic acid. Through selection and breeding the first low-erucic *B. napus* variety, 'Oro,' was developed in 1968, producing an entirely new but natural oil (Table 2). The change in fatty acid composition was achieved by genetically blocking the biosynthetic pathway for fatty acid carbon-chain elongation, from oleic to eicosenoic to erucic, as the oil is laid down in the developing seed. Pilot-plant tests indicated that the new oil was ideal as a salad and cooking oil, and steps were taken to contract its production. Unfortunately, that year tanker loads of sunflower oil were dumped by the Soviet Union on the world market and those plans were shelved. Despite this setback, the breeding program to develop a low erucic *B. rapa* variety was continued, producing the first low erucic variety, 'Span,' in 1971.

Nutritional studies on rapeseed oil continued and in the fall of 1970 the Second International Rapeseed Congress was held in Canada. Nutritionists in Europe and Canada reported abnormal numbers of heart lesions in laboratory animals fed high levels of rapeseed oil. The high content of erucic acid was considered the cause. Again we were in danger of losing our markets. Agriculture Canada immediately made the decision to take what little seed we had of the low-erucic varieties of both species for winter increase in California. The returning seed was sown in the spring of 1971 and the total conversion of the 4-million-acre crop was underway. With the cooperation of the entire industry, the conversion was complete by 1973. As indicated by the earlier pilot-plant tests this entirely new, edible oil was found to have superior properties as a salad and cooking oil as well as being suitable for margarine and shortening blends. As a result, domestic use increased from 19% in 1970 to 49% in 1997 (Fig. 1).

Opening of the US Market

Although the switch to the low-erucic oil removed the stigma from Canadian rapeseed oil, the United States market was closed to canola because rapeseed oil had never been in widespread use there and was not included in the US "GRAS" list of foods (generally regarded as safe). Since the US market was potentially very large, the industry requested that research required to obtain GRAS status be undertaken. A large body of nutritional data was assembled and the petition was successful; GRAS status was granted in 1985. The results of these studies were compiled and published in a book, *High and Low Erucic Acid Rapeseed Oils* (Kramer *et al.*, 1983).

The opening of the US market brought a surprise. We breeders had bred better than we knew. Nutritionists decided that oils high in polyunsaturated fatty acids were no longer the "best" for human consumption. Further, for good health, saturated fatty acids were to

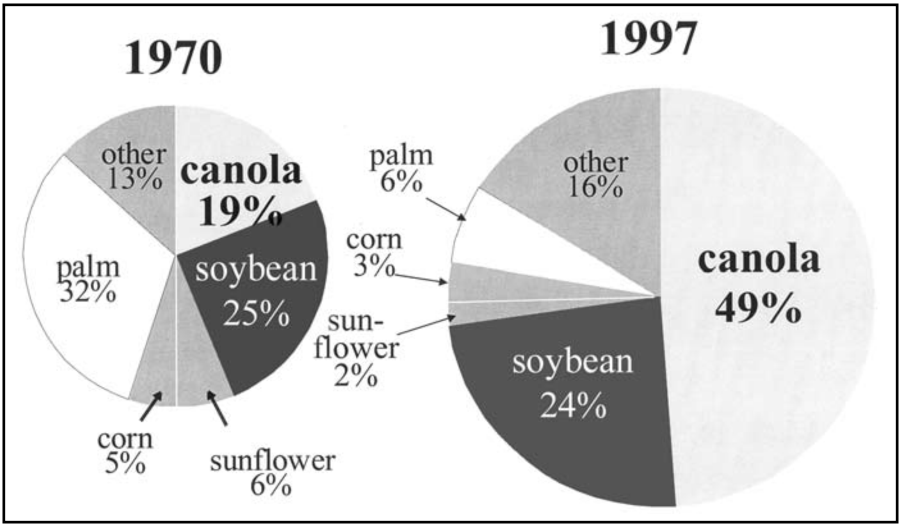

Figure 1. Canadian vegetable-oil usage

be avoided. Since low erucic rapeseed oil had the lowest content of saturated fatty acids of any vegetable oil (Fig. 2) it attracted the interest of large food companies. In addition to the low saturate level, the new oil also had a high concentration of the monounsaturated fatty acid oleic, which lowers the undesirable low density lipoproteins (LDLs) without affecting the desirable high density lipoproteins (HDL's) while retaining suitable levels of the essential, polyunsaturated fatty acids, linoleic and linolenic. Thus the oil was quickly promoted as a highly nutritious specialty oil, receiving the American Heart Foundation's 1989 Food Product of the Year Award and the American College of Nutrition's 1989 Product Acceptance Award.

Decreased Linolenic Acid

As successful as the new oil was, the industry wanted a reduction in the level of linolenic acid from the standard 8 to 10% to less than 3% of the total fatty acids to improve its keeping quality and to reduce the need for hydrogenation. This was accomplished through mutation breeding and the first low-linolenic variety, 'Steller,' was released in 1985. Now company breeders have taken it one step further and produced varieties with an even higher level of oleic acid coupled with low linolenic acid values (Table 3). This oil is gaining rapid acceptance both in North America and Japan and in time will likely make up about half the canola market. A further nutritional improvement will likely soon appear since Dow AgroSciences has patented a canola oil for which they claim zero saturates (Table 3).

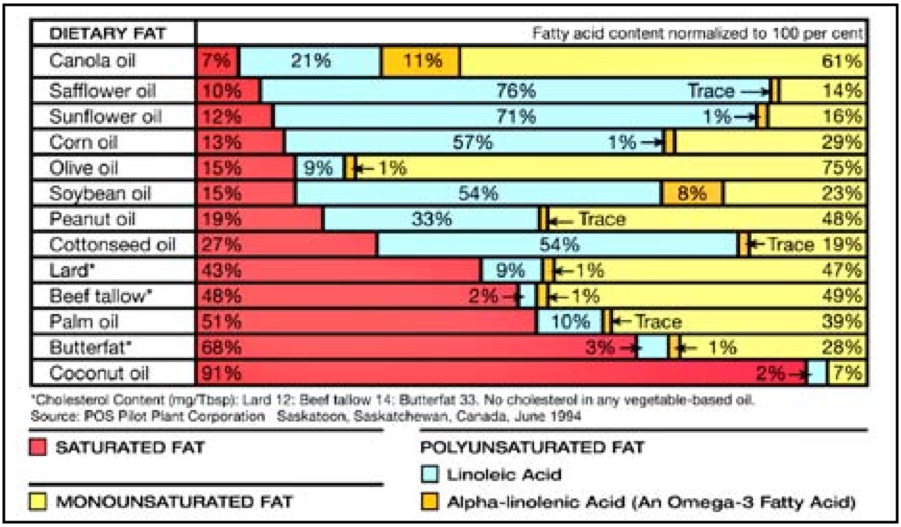

Figure 2. Comparison of dietary fats.

Table 3. Fatty acid composition of normal and modified rapeseed/canola oil in commercial production

	Fatty acid composition (%)							
Oil type	**16:0**	**16:1**	**18:0**	**18:1**	**18:2**	**18:3**	**20:1**	**22:1**
Canola	4	<1	2	62	20	9	2	<1
Low linolenic	5	<1	2	64	25	<3	1	<1
High oleic/Low linolenic	4	<1	2	78	12	2	<1	<1
Zero saturate	<1	<1	<1	85	12	2	<1	<1
High erucic	2	<1	2	13	12	9	7	54

Meal Utilization

Although the development of a superior edible oil was achieved by 1971, a major market constraint remained, namely the utilization of the high-protein meal remaining after oil extraction. Even though the protein quality of rapeseed meal was equal to that of soy meal, feed efficiency and weight gains with swine and poultry were well below expected levels. This restricted the amount of meal that could be fed and, in turn, limited the amount of seed that could be processed. The problem was associated with the presence in the seed of glucosinolates. These sulphur compounds, of which about ninety are known, give the desired flavor and odor to cabbage, turnips, mustard and other cruciferous crops. However, the plant accumulates and concentrates these compounds in the seed, typically at 100 to 150 μmoles/g. As a result, the nutritional value and palatability of the meal is reduced when fed to non-ruminants such as swine and poultry.

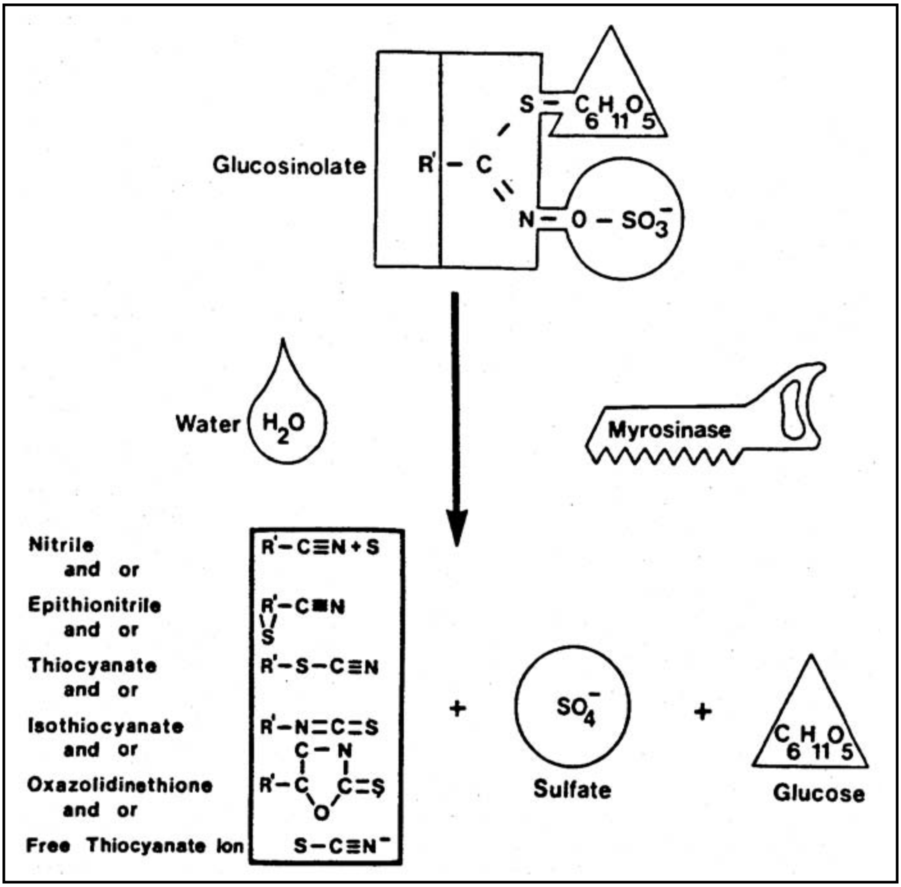

Figure 3. Products of myrosinase hydrolysis of the glucosinolates.

When the cells of rapeseed are broken with moisture present, the glucosinolates are hydrolyzed by myrosinase—an enzyme present in all cruciferous seeds—and sulphur, glucose and isothiocynates are released (Fig. 3). The isothiocyanates are active goitrogens that interfere with iodine uptake by the thyroid gland in swine and poultry, resulting in goiter and poor growth. Early studies showed that the problem could be partly overcome by heat inactivation of the enzyme as the first step in the oil-extraction process. However, some hydrolysis still occurred in the gut. Thus, the ultimate objective was to breed varieties free of glucosinolates. Again, new chemical methodologies had to be developed to rapidly and accurately measure the amounts of the various glucosinolates in small samples of seed. Using these new techniques, breeders were able to genetically block the glucosinolate biosynthetic pathway from the methionine and tryptophane precursor amino acids, resulting in the first low-erucic, low-glucosinolate variety of *B. napus*, 'Tower,' in 1974. However, it took another 3 years to produce the first double-low *B. rapa* variety, 'Candle,' so that the second complete crop changeover could occur.

Global-Market Acceptance

By 1980, the 5-million acre commercial crop was largely converted to the new double-low varieties, thus removing the constraint associated with the feeding of the meal. Animal nutritionists at several universities conducted extensive studies to convince both domestic and foreign feed formulators that the low glucosinolate meal was, indeed, a safe, wholesome and economic high-protein supplement. Eventually Europe, using Canadian germplasm, converted to canola-quality varieties in 1988–1989 and Australia in 1990, while China, India and Pakistan are expected to achieve conversion within the next decade. The market impact of these quality modifications was dramatic, not only domestically (Fig. 1) but also for exports of oil and meal (Fig. 4) as well as seed (Fig. 5). Improvements in seed yield as well as quality resulted in a better return to producers and an expanding production base (Fig. 6). Surprisingly, these significant quality changes were made without adversely affecting the overall agronomic performance of the crop. From the outset in this series of crop changes, Canada consulted closely with its major customer, Japan, meeting with counterparts at least twice a year.

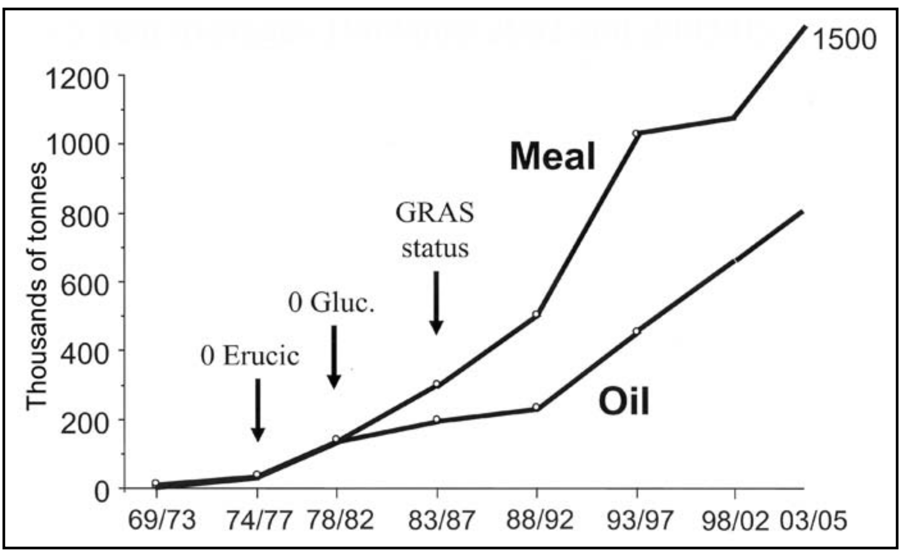

Figure 4. Five-year averages of Canadian rapeseed/canola oil and meal exports.

As a result of the nutritional upgrading of the oil and meal, a new name was required to distinguish these products from the old-style rapeseed. "Canola" was coined, trademarked and defined.

"Canola" Coined

As a result of the nutritional upgrading of the oil and meal, a new name was required to distinguish these products from the old-style rapeseed. "Canola" was coined, trademarked and defined as seed, oil or meal having less than 2% erucic acid in the oil and less than 30 μmole/g of aliphatic glucosinolate in the oil-free, moisture-free meal. This definition is due to be further refined to better reflect today's commercial crop. The new definition reduces the erucic acid content to less than 1% and establishes a maximum of 18 μmole/g of all glucosinolates in whole seed. In the oil-free meal, the maximum will be 30 μmole/g, with both seed and meal at 8.5% moisture. As a result of reducing the glucosinolate content from the original 100 to 150 μmole/g, canola meal can now be fed as an economic high-protein supplement.

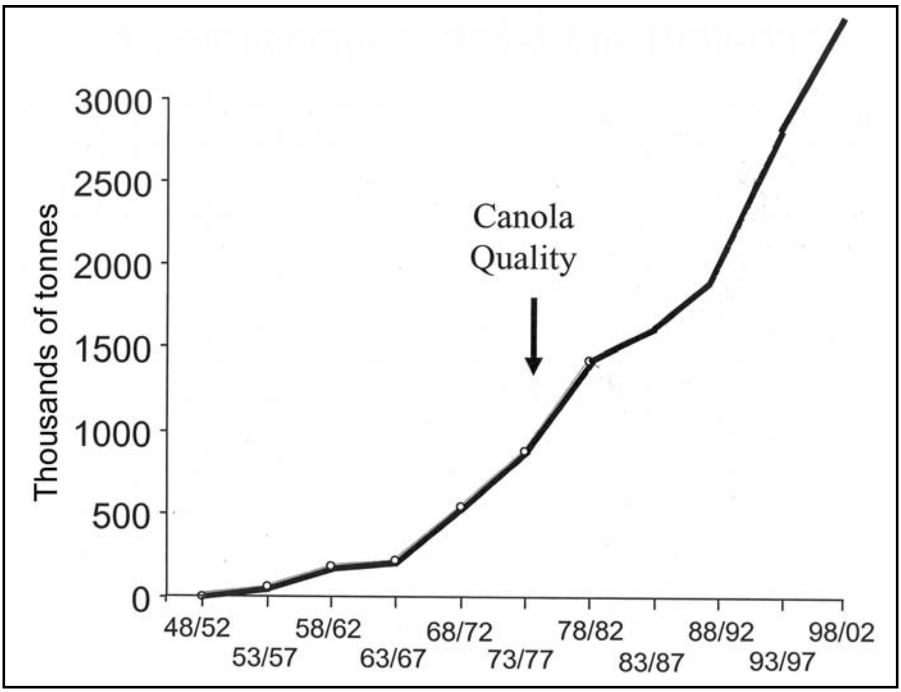

Figure 5. Five-year averages of Canadian rapeseed/canola exports.

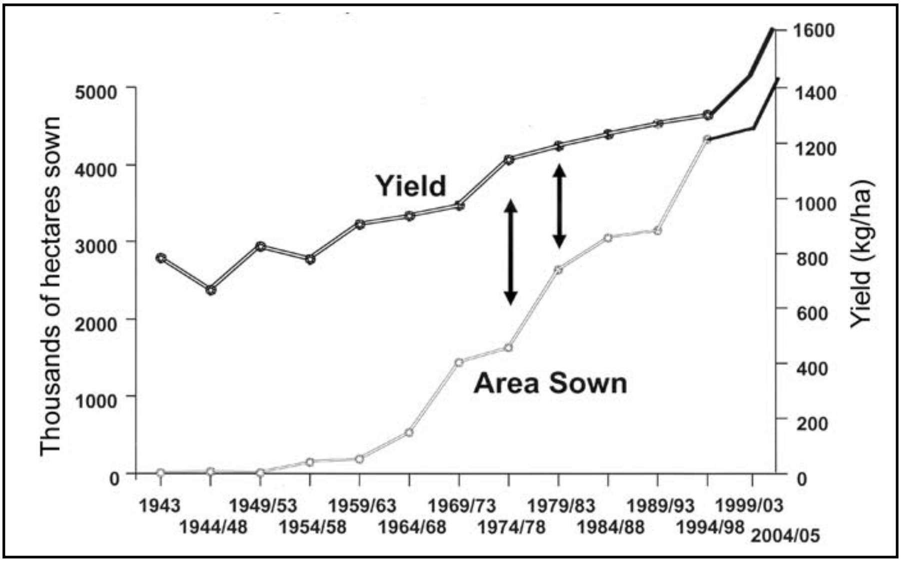

Figure 6. Five-year averages of area sown and yield of rapeseed/canola.

The development of canola is considered a success story because it diversified Canada's agriculture base, eliminating dependence on oil imports and increasing returns to producers while expanding markets at home and abroad. In addition, it resulted in the establishment of a large rural-based, value-added oilseed crushing and refining industry. Eight canola-oil extraction plants are now distributed across the prairie provinces, processing some 3 million tonnes/year of seed, with expansion planned or under way. Canola has also responded to all the biotechnologies with 90% of the crop herbicide-tolerant; hybrid varieties now occupy about 30% of the area planted. The story is not over yet as canola is a preferred biodiesel oil source for northern climates because of its low content of saturated fatty acids.

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KEITH DOWNEY was born in Saskatoon, Saskatchewan. He obtained his BSA and MSc from the University of Saskatchewan and PhD from Cornell University. He joined Agriculture and Agri-Food Canada in 1951 where he developed many outstanding rapeseed/canola and condiment mustard varieties. He is widely known as one of the "fathers" of canola and has been instrumental in improving nutritional quality and customer-acceptance of oil and meal from *Brassica* oilseed crops. He has authored over 200 scientific and technical papers, several book chapters and co-edited the book *Oil Crops of the World*.

Dr. Downey has received numerous awards and medals including Officer of the Order of Canada, Fellow of both the Royal Society of Canada and the Agriculture Institute of Canada, the Eminent Scientist Award from the Internation Rapeseed Congress, the James McAnsh Award from the Canola Council of Canada and the Clark-Newman Award from the Canadian Seed Growers Association. Recently, he was inducted to both the Saskatchewan and the Canadian Agriculture Halls of Fame.

In recent years, as senior research scientist emeritus at the Agriculture and Agri-Food Canada Research Centre in Saskatoon, Downey has investigated the impacts on agriculture of biotechnology and gene-flow.

India: New Products and Opportunities

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Sathguru Management Consultants
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India's economy is among the fastest growing in the world. During the past 10 years, it has grown consistently at 6% to 8% annually. However, although growth in the industrial and services sectors has been above the national average gross domestic product growth rate, the rate of growth in agriculture in the recent past has been less than 2%. A national mission is to revive the under-performing agriculture sector by:

- Enhancing farm production and food quality
- Reducing waste.

The strategy involves:

- Attracting investments that will trigger high growth in agriculture and in the processed-food industry
- Partnering in global research initiatives that will help India to acquire as well as provide technologies
- Nurturing innovation that will help to create competition and provide opportunity for development of commercialization of new products.

Embracement of Agricultural Biotechnology

Early on, India realized the need to apply tools and techniques of agricultural biotechnology to enhance agriculture and increase food production. Accordingly, the country has permitted growing of bollworm-resistant transgenic cotton since 2003, with wide adoption of the technology by farmers. During the year 2006, about 3 million hectares of transgenic cotton are expected to be planted, making the country the second-largest grower of genetically engineered cotton in the world.

Some fourteen crops are currently being developed with various traits incorporated for mitigating biotic and abiotic stress factors. There are also efforts to enhance nutrition that can provide relief to mal-nourished children.

The fruit- and shoot-borer-resistant eggplant is an early food crop being tested in farmers' fields in 2006. The fruit and shoot borer can cause crop losses of 30% to 60%.

This single transgenic event in eggplant has the potential to bring economic gains of over $300 million for the region.

Consortium Approach

This single transgenic event in eggplant has the potential to bring economic gains of over $300 million for the region. This project is supported by the Cornell-managed Agricultural Biotechnology Support Project II (ABSPII), funded by USAID and regionally supervised by Sathguru, a consortium partner within ABSPII. The project aims for the first time to provide technologies to the public sector by delivering transgenic seeds to resource-constrained farmers who would otherwise be denied such access. ABSPII has also facilitated transfer of technologies to other Asian countries including Bangladesh and the Philippines.

Scientists in India, the United States, Bangladesh, Indonesia and the Philippines have combined their efforts and expertise to develop drought- and salinity-tolerant rice, virus-resistant groundnut and sunflower, late-blight-resistant potato and virus-resistant papaya.

The consortium approach has resulted in conserving precious resources, enhancing ability to develop products and sharing research outcomes for public-good application.

The consortium approach now being adopted by many Indian research enterprises—sharing technologies and co-operating in product development—has resulted in conserving precious resources, enhancing ability to develop products and sharing research outcomes for public-good application.

Socio-Political Issues

While transgenic technologies are certain to provide gains for Indian agriculture, to maximize these gains it is essential to address certain currently prevailing constraints. Extensive creation of public awareness, educating science writers and journalists appropriately in terms of risk and benefit factors and harmonizing the regulatory framework will help to ensure systemic adoption of the technology.

A Key Player Regionally and Globally

India will be a key player in harnessing and applying agriculture biotechnology inventions, tools and techniques to enhance food production and also to contribute to alleviating global poverty by providing access to invaluable technologies to other needy nations. Young, multi-faceted talent provides the opportunity for India to be the research destination of the world.

VIJAY VIJAYARAGHAVAN is a certified management consultant and a fellow of the International Council of Management Consulting Institutes (ICMCI). He holds a masters and fellowship in public accounting and management consulting, with focus on strategic and technology management consulting.

Mr. Vijayaraghavan is the chief executive of Sathguru Management Consultants Pvt Ltd, based in Hyderabad, India. Sathguru advises government organizations, multilateral and bilateral development institutions, private enterprises and NGOs in several countries across the Asian region. He is engaged in shaping number of policy initiatives in life sciences for India and is a member of national committees constituted for this purpose.

Sathguru is associated with the Cornell-in-India program, of which Vijayaraghavan is a director. The program encompasses several countries in Asia. Vijayaraghavan is also regional coordinator or the South Asian (India and Bangladesh) activities of the Agricultural Biotechnology Support Program II.

New Perspectives for Agricultural Biotechnology in Brazil

Ana Claudia Rasera da Silva
Alellyx Applied Genomics
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In Brazil, the production of ethanol from sugar cane has increased 3-fold in the past 25 years. The current average yield is 6,000 L/ha. However, in line with the Kyoto Protocols, we will have to increase production at least 3-fold again by 2010 to satisfy projected needs.

Production of ethanol from sugar cane in Brazil results in an output of eight times more energy than is put in. In contrast, ethanol from corn kernels results in an energy output of 1.3–1.8 compared to 1.0 invested. We can produce up to 7,000 L/ha, which again compares favorably with corn kernels at 3,500 L/ha. Brazil also has greater sugar-cane production at lower prices in comparison with Australia, South Africa, India and Cuba.

These advantages accrue from Brazil's geographical location and plentiful supply of rainfall, with ideal conditions of sunlight availability and temperature. Plenty of arable land is available and labor costs are low, which will contribute to increased production. Also we have scientific expertise in genetics and agriculture technology that has contributed to the increased productivity of sugar cane as a crop and improved efficiency of ethanol synthesis.

Need for Greater Productivity

However, even greater productivity will be needed to produce enough ethanol to meet global demands in the near future. One possibility is to use cane bagasse as a source of cellulose for fermentation to produce sugars and then ethanol. This will be similar to how corn starch is being used in the United States.

An alternative means of using cellulose to produce ethanol is to employ enzymes that can hydrolyze it for conversion to sugar. Bagasse, the residue after sugar extraction, is a good source of lignocellulosic material and a positive aspect is that it is already at the mill. There is no need to transport it for processing. Bagasse represents about 30% of the total biomass of sugar cane. Currently it is burned to produce steam for electricity.

Today, 1 ha yields 85 tons of cane that is mashed to produce juice. The juice is fermented to produce up to 7,200 L of ethanol. Including bagasse, this could be increased to 15,000 L/ha. Another 2-fold increase might be gained by breeding cane of higher fiber content, so-called "energy cane." Conventional cane produces around 70 to 120 tons/ha. High-fiber or energy cane might provide 140 to 240 tons/ha, doubling the yield of ethanol.

Two new companies were established in Brazil with the aid of venture capital: Allelyx and CanaVialis.

New Biotech Companies

With these objectives in mind, two new companies were established in Brazil with the aid of venture capital. Allelyx, a plant-biotech company, was founded in 2002 by scientists at the Universities of Sao Paulo, Campinas, and Sao Paolo State who had sequenced the genome of *Xilella fastidiosa*, the causative agent of variegated chlorosis in citrus. CanaVialis is a sugar-cane breeding company, founded in 2003 by scientists at the Federal University of Sao Carlos. CanaVialis scientists, with over 30 years experience in sugar-cane breeding, have created the varieties that today make up over 60% of the sugar cane now planted in Sao Paulo state. These varieties are responsible for recent increases in sugar and ethanol productivity.

Allelyx is located at Campinas with about 130 employees, a third of whom are responsible for plant transformations. We are also strong in bioinformatic analyses with foci on sugar cane, citrus and eucalyptus. CanaVialis is using traditional breeding methods to generate new varieties of sugar cane; it has the world's largest breeding program for sugar cane. They have an experiment station with a huge stock of germplasm, close to the equator in a climate ideal for crossing cane varieties and maximizing breeding efficiency.

Allelyx provides the genes while CanaVialis provides the germplasm.

Allelyx deals with gene discovery, proof-of-concept and also with product development and regulatory issues, while CanaVialis works directly with producers to facilitate future commercialization of new varieties. In short, Allelyx provides the genes while CanaVialis provides the germplasm.

Proving Concepts

At this stage we are working mostly with model plants to prove concepts while developing protocols for efficiently transforming our target crops. We are leaders in terms of transformation protocols for sugar cane, citrus and eucalyptus, and have already proven some concepts in plant models:

- genes introduced in tomato and sugar cane increase sucrose content,
- sugar cane has been made resistant to the mosaic virus,
- lignin content in tobacco has been decreased, and
- xylem-bundle thickness and cellulose content in tobacco has been increased.

We are now working to introduce these traits to the target crops.

Some promising results have been obtained in terms of increasing sucrose content of sugar cane. Preliminary Brix data indicate that we have almost doubled it. Also, we have interesting results for drought tolerance in tobacco, which will be important for the expansion of sugar-cane production into the Cerrado, where rainfall is significantly less than in Sao Paulo to the south.

ANA CLAUDIA RASERA DA SILVA is a biochemist with a PhD in molecular biology from the University of São Paulo (USP) and postdoctoral experience in molecular chaperones at the Rockefeller Laboratory of the Memorial Sloan Kettering Institute in New York. She worked for 8 years as assistant professor of biochemistry at USP, during which period she participated in the *Xylella fastidiosa* and *Leifsonia xyli* pv. xyli Genome Projects and coordinated the *Xanthomonas axonopodis* pv. citri Genome Project; the latter is the causative agent of citrus canker.

Dr. da Silva is one of the founders of Alellyx Applied Genomics, a Brazilian agricultural biotechnology company focused on sugar cane, *Eucalyptus* and *Citrus*, where she is responsible for the Citrus Program and the DNA Technology Department. Her team discovered and sequenced the causative agents of two citrus viral diseases: citrus sudden death and leprosis. Currently she is investigating ways of optimizing the vigor, productivity and yield quality of citrus groves.

Chinese Agricultural Biotechnology in the Field

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China, one of the largest agricultural countries in the world, has made significant achievements in agricultural production. We use about 70% of arable land to feed 20% of our population. However, since 2000, production has been stable, whereas the population continues to increase, therefore we face challenges, as in India. The first is population. We estimate that it will increase to 1.6 billion around the year 2020, therefore we need to increase agricultural production commensurately. And then we have challenges in terms of arable land and water resources.

Imports and Exports

After China joined the World Trade Organization in 2001, importation of agricultural products increased dramatically and the trade deficit climbed to over US$5 billion in 2005. Three major problems characterize US/China trade relations. First is the United States-to-China deficit in agricultural goods. Second is the China-to-United States deficit, which includes textiles and other industrial goods. The second trade issue is the value of Chinese money. The third problem is intellectual property (IP) rights.

In 2005, China imported 27 million tons of soybean from the United States, Brazil and Argentina, almost 40% of the total consumption in China (which produced about 60 million tons). Importation of soy from the United States began in 1995, mostly from Iowa and Wisconsin.

In 2001, China made labeling of GM seed mandatory. US companies were unable to quickly meet the imposed standard, importation dropped precipitously in that year; however, it came back in 2002, 2003 and 2004.

Cotton is the second most important crop imported by China. Although we are one of the largest producers of cotton, involving 200 million farmers, 15% of exports are textiles. In 2005, China's cotton importation increased dramatically; it increased from 3 million to 5 million tons between 2000 and 2005. Corn and rice are also imported.

Investments in Agricultural Biotechnology

The Chinese government has made significant investments in agricultural biotechnology. In an attempt to ensure food security, research funding has been doubling every 5 years. China is second only to the United States in terms of federal funding of plant biotechnology. In contrast to India, in which multinational companies including Monsanto are operating, China has little investment in plant biotechnology from the private sector, possibly due to concerns over IP.

China is second only to the United States in terms of federal funding of plant biotechnology.

Thus, plant biotechnology is developing rapidly, with much activity in field trials and the process of commercialization. China is number five in terms of production and commercialization of transgenic crops (*i.e.* cotton) in the world after the United States, Argentina, Brazil and Canada. After the government approves transgenic rice for commercial production, China will quickly occupy the number-two position.

In total, about 700 applications have been approved for field trials and about seventy-five commercialization licenses have been granted. The largest number is of transgenic cotton, which has been released in more than ten provinces. However, about thirty species of transgenic plants being tested in the field, including cotton, rice, wheat, corn, soybean, potato, oilseed rape and tobacco. Also, over 30,000 transgenic poplar trees are under trial in the Beijing area.

Over 60% of cotton grown in China is genetically engineered.

Transgenic cotton was first grown commercially in 1996, and today over 60% of cotton grown in China is genetically engineered. It is close to 100% transgenic in the Yangtze River basin. Transgenics are not used in Xingjian province, although it is a major production area for cotton, because nematode infestation is not a serious problem.

Imported Concerns

As in other Asian countries, public concern over the safety of GMOs is a problem in China. This problem came from Europe; 1998 and 1999 were difficult years. Greenpeace published a magazine, available free of charge, which was sent to officials in China and members of the scientific community. Particular attention was focused on transgenic rice. China is the major rice producer globally. Over 600 million Chinese farmers live on rice and it is also vitally important globally. Research on transgenic rice has been in progress for over 20 years. Genetically engineered rice is being field-tested for resistance to insects, bacterial blight, and fungal rust, and for salt and herbicide tolerances, and with nutritional improvements including golden rice resulting from collaboration with Ingo Potrykus, and varieties resistant to rice dwarf virus from my laboratory.

We are now in the last phases of preproduction trials of transgenic rice. In November 2004, the final committee of scientists approved transgenic rice for commercialization, and we await approval by the Ministerial Conference, which consists of representatives of seven ministries including Agriculture, Science and Technology Involvement, and Import/Export. We expected approval in May 2005, but Greenpeace acquired seeds and sent them to GeneScan, an analytical laboratory in Germany. A PCR assay revealed a *Bt* gene, which drew press attention globally. Immediately, Japan and Korea, banned importation of rice from China, in response to which the Conference postponed commercialization and we still await approval, despite the fact that our scientific committee again approved *Bt* rice in November, 2005.

In early 2006, Greenpeace announced detection of GM rice in Chinese-made baby food and is publicizing the "scandal of illegal GM rice" on their website. Thus, the situation in China is getting more and more difficult. In contrast, the situation is good in the United States; however, it remains difficult in Europe and increasingly so in China.

A common complaint is that GM food is unsafe, yet *Bt* toxin has been used in China since the 1960s for insect control on vegetables, with no reports of poisoning. Over 2 billion people in the Unites States, Argentina and China have been exposed to transgenic soybean with no reports of toxicity. (We import transgenic soybean, but are not allowed to grow it.)

Environmental safety is also a concern. Greenpeace has attempted to convince the government that genetically engineered crops adversely affect the environment. The fact that many people have been poisoned by ingestion of pesticides is generally ignored. It can be argued that since *Bt* crops save human life, they actually improve the environment. Significantly more insects are present and increased insect diversity exists in fields of transgenic cotton because less pesticide is applied. More people are poisoned and die as a result of exposure to insecticides used on non-transgenic cotton and rice than with *Bt* counterparts.

The issue of beneficiary is another source of complaint. Benefits accrue to farmers and to the production company—often Monsanto is the focus of discontent—rather than to the consumer.

Labeling

Labeling is another contentious issue. In the United States, labeling is voluntary on the part of the producer, therefore the situation becomes complicated where products are being exported. China enacted a law in 2002 enforcing labeling. Soybean oil has to be labeled to indicate its GM source even though it does not contain any transgenic component. This can be confusing for consumers. Furthermore, many people in China are illiterate; the extra cost involved in labeling is, in many cases, of no utility.

Agbiotech and Global Needs

Part of my job is to convince people that this technology is useful, which has become difficult as a result of Europe's influence. If the European Union would be accepting of GMOs, China, India, Thailand and African countries would benefit. In many parts of the world people are hungry, yet their ability to feed themselves is being compromised by others who live in abundance. I hope that more attention will be paid to these poor countries, especially to hungry countries, so that this technology can be made available to help people help themselves and help the environment.

ZHANGLIANG CHEN—A pioneer in genetic engineering of plants—received his PhD in Roger Beachy's laboratory at Washington University, St. Louis, in 1987. He has served as vice president of Peking University and as director of the China National Laboratory of Protein Engineering and Plant Genetic Engineering, one of China's largest centers for R&D in agricultural biotechnology. Actively involved in biosafety issues, he is a member of the China National Agrobiotechnology Biosafety Committee, which approves field trials and commercialization of genetically engineered crops. He has (co)authored seven books and some 200 research papers.

Dr. Chen has been the president of the China Agricultural University since 2003. He also serves as chair of the Plant Biotech Committee of UNESCO, as a consultant for the International Society for Plant Molecular Biology, and as a member of the Sino-Euro Administration Committee for Biotechnology Cooperation. He was recently elected vice chairman of the Council of Scientific Advisers of the International Center for Genetic Engineering and Biotechnology in Italy.

Globalization of European Biotechnology: Commercialization of Agbiotech Products Despite Political and Legal Restrictions

Peter Welters
Phytowelt GreenTechnologies GmbH
Nettetal, Germany

Agricultural biotechnology has its roots in Europe. The basic technology–*Agrobacterium tumefaciens*-mediated gene transfer into plants—was discovered and developed by Jeff Schell and Marc van Montagu in Cologne, Germany, and Ghent, Belgium. Despite these successful research activities and patenting of the technology, efforts to put these inventions into practice and launch profitable products on the European market were unsuccessful due to fierce and continued protests from non-governmental organizations (NGOs) prejudicing the general public and political leaders against genetically modified (GM) plants.

The EU moratorium on approval of GM plants in 1998 was a particularly serious blow.

The first commercial cultivation of GM plants took place in 1995 in the United States. Since then, the industry has seen double-digit growth every year, but only outside of Europe. The EU moratorium on approval of GM plants in 1998 was a particularly serious blow. Most biotechnology companies, especially those financed by venture capital, went out of business, lacking strategies for surviving a 6-year-period without launching products. Even large multinationals fell victim, and had to merge or were sold to competitors to increase shareholders' values. Small and medium-sized companies survived only if they had products other than GM plants in their portfolios and with global markets.

Successful Business Strategy

Phytowelt GreenTechnologies offered services and contract research in addition to developing products for industry and consumers. Our main technologies—the proprietary genetic marker system ISTR, patented genes to improve plants and tissue-culture technologies such as somatic hybridization—led to projects with ornamental, food and fodder plants. Furthermore, we improved procedures for the production of phytopharmaceuticals and platform chemicals for our clients in the chemical and pharmaceutical industries.

The success and steady development of the company are based on an international orientation and embracement of globalization since the beginning. Clients in Japan, New Zealand, Canada, United States and Europe are proof of this strategy. Another critical factor was the self-sustained financing by private shareholders, assignments and contracts. Grants from public institutions were used to implement new technologies.

Political Obstacles

Nowadays, the European biotech landscape shows an uneven distribution of companies, with concentrations along the Rhine and the River Thames as well as uneven application. Medical and pharmaceutical biotech companies outnumber, by a factor of five, those with an agricultural orientation.

More research has been demanded to prove the safety of GM crops, serving to postpone their introduction.

Besides the lack of consumer acceptance, absence of consistent and reliable legislation prevent commercialization of GM products in Europe. The discussion revolves around thresholds, labelling, traceability, monitoring, coexistence, admixture, liability and biopatents without reaching firm conclusions to provide a legislative framework. Instead, more research has been demanded to prove the safety of GM crops, serving to postpone their introduction. Interest on the part of the industry to conduct appropriate research has declined in recent years. The number of field trials (Figure 1) reached its peak in 1997/1998, and since then has decreased significantly. A small increase in 2006 may indicate a turning point, but it is too early to be certain.

Spain leads the current EU member states with 53,000 ha planted to GM crops in 2005, and with an increase in 2006. Romania, which will become an EU member in 2007, has an even greater area, of GM soybean. However, because the cultivar is not approved within the EU, its cultivation will be forbidden once Romania enters EU-25. Three other European states, Germany, France and the Czech Republic, together had around 1,000 ha of GM crops in 2005. This probably hit the 10,000-ha threshold in 2006, largely because of ten-fold increases in France and the Czech Republic; Germany planned only a doubling to around 900 ha.

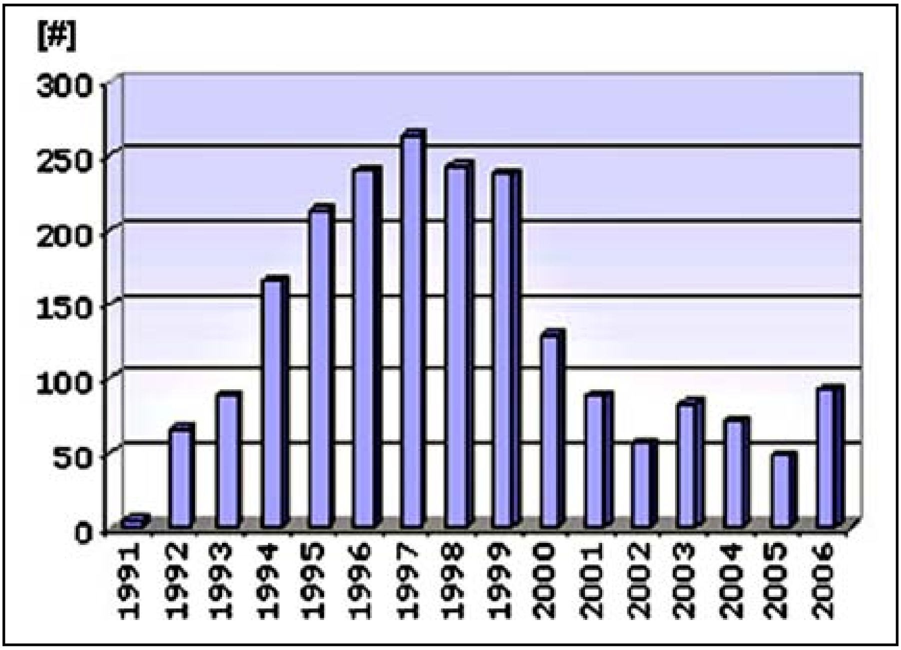

Figure 1. The number of field trials of GM plants increased steadily until 1997. The European Commission's 1998 moratorium, preventing commercialization of GM plants, adversely affected R&D.

In the European Commission's Plants for the Future *program, the emphasis is on bioenergy and biobased chemicals to promote development of a biobased economy.*

End of the Moratorium

A turning point occurred in 2004 when the EU ended its moratorium and approved importation of GM corn. In 2005, Germany turned its attention to GM after the Green party failed to win re-election in their last two strongholds, the NRW state government and the federal government of Germany; three varieties of GM corn were approved for cultivation within the first 100 days of the new federal government. Coincidentally, Phytowelt sold the first license of its proprietary parthenocarpy technology to a US seed company. But the general situation in Europe is unchanged: to stay in business, produce either non-GM products (Figure 2) or non-food value-added products like monoterpenes (Figure 3). This is also the strategic line of the European Commission. In their *Plants for the Future* program, the emphasis is on bioenergy and biobased chemicals to promote development of a biobased economy. Their decade-long timeframe indicates that even in the Commission no one expects short-term implementation of the technology in Europe. And to avoid the term "genetic engineering" "precision breeding of renewable resources" has become the fashionable, politically correct term.

Figure 2. Non-genetically engineered, non-food products currently have the best chances of success on the European market. Despite the end of the moratorium, GM plants are still underrepresented.

Industrial Plant Biotechnology

A fairly new trend, but not a new industry, is so-called "white" or "industrial" biotechnology in Europe. Because of the success of some European companies (*e.g.* DSM, Novozymes, BRAIN), this field is considered as more promising than biotechnology of plants for food and feed. In the beginning, companies tried to avoid being connected with genetic engineering of plants. But it is becoming accepted that industrial biotechnology needs to be combined with plant biotechnology to fully exploit its potential.

Instead of using agriculture only as a source of feedstock for fermenters in the form of sugar and other low-value commodities, it was realized that plants can deliver a whole range of complex chemical entities. Precursors for steroid hormones and cancer medication (*e.g.* taxol) for the pharmaceutical industry and polymers like caoutchouc, a polyterpene, for the rubber industry are already being delivered by plants. Mint plants can produce a

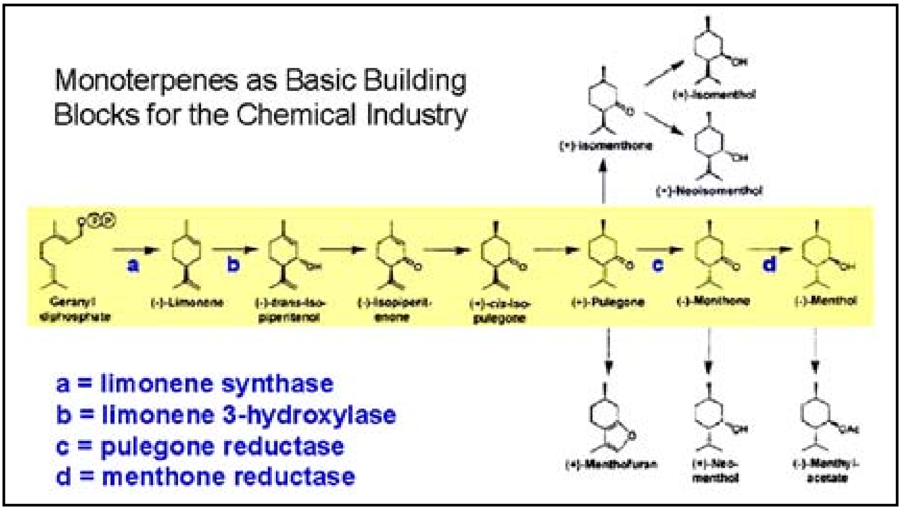

Figure 3. The biosynthesis of menthol as an example of the production of platform chemicals in mint plants exploiting their biodiversity for the sustained production of chemicals; a, b, c and d are known enzymes of the biosynthetic pathway that can be genetically modified to direct the production of a particular monoterpene.

whole range of monoterpenes depending on the variety, thus biodiversity may be exploited to increase the use of renewable resources for sustained production of chemicals (Figure 3). With genetic engineering, plant biotechnology can combine the primary production of agriculture and the conversion technology in fermenters to shorten the process and reduce costs. By providing higher concentrations of basic precursors, such plants will improve fermentation processes. Due to removal of contaminating by-products by inhibiting their synthesis *in planta*, the higher purity of products from GM plants will secure their usefulness to the chemical industry.

Plant biotechnology companies are again the target for multinational corporations to improve their pipelines.

Financial Aspects

Encouraging signals from the technological side are supported by recent news of mergers and acquisitions. Plant biotechnology companies are again the target for multinational corporations to improve their pipelines, *e.g.* BAYER incorporated Icon Genetics, BASF bought CropDesign in Belgium, and Biolex (USA) acquired Lemnagene (France). The formation of Phytowelt GreenTechnologies was a merger of equal partners, Phytowelt and GreenTec, the latter a spin-off of the Max-Planck-Institute for Plant Breeding Research in Cologne. The increased interest in plant biotechnology from the financial community is also shown in a new round of financing for Novoplant, Germany: they raised 3 million euros. And new companies are being founded, such as Solucel, a combined effort involving Finnish and Belgian governmental institutions.

Conclusion

These examples show that biotechnology is on the rise again in Europe. Instead of being paralyzed by the scaremongering of anti-GMO-activists, we should spread the good news. There are enough examples to show the benefits of applying genetic engineering of plants and thereby convince the general public. We have only to inform people correctly and constantly about the progress and the benefits of this new technology. Millions of farmers worldwide cannot be wrong!

Labelling should be mandatory for products improved by genetic engineering (Figure 4) to show that we are proud of the technology and convinced of its benefits. Conferences like NABC's and ABIC's are important and supporting them helps to improve acceptance and distribution of this beneficial technology. NABC 19 will convene in Brookings, South Dakota, May 22–24, 2007, and ABIC2007 in Calgary, September 23–26, 2007.

Figure 4. GO indicating modern, innovative genetic engineering to improve a product labelled according to quality standards defined by the academic and industrial communities.

AFTER STUDYING chemistry, biochemistry and food chemistry in Germany, Peter Welters spent 4 years at the Max-Planck-Institute for Plant Breeding Research, there obtaining his Diploma and PhD. He worked in Jeff Schell's group on promoter control in the legume/rhizobia nitrogen-fixing symbiosis. After 3 years at the University of California, San Diego, in the laboratories of Maarten Chrispeels and Scott Emr, researching protein-transport regulation in plants and yeasts, he was chosen as head of the *Production of Pharmaceutical Proteins in Plants* project in Rouen, France.

Dr. Welters's innovative ideas led to the foundation of Biotechnology and Molecular Biology, which became Phytowelt GmbH in 1998. Four years later, he became CEO of GreenTec GmbH, a spin-off company of the Max-Planck-Institute, founded by Schell, Klaus Hahlbrock, Frederico Salamini, and Heinz Saedler.

Since January 2006, Welters has been CEO of Phytowelt GreenTechnologies GmbH, a fusion of GreenTec and Phytowelt, located in Nettetal (head office) and Cologne (R&D). The company offers laboratory and know-how services in agricultural biotechnology, *e.g.* somatic hybridization, tissue culture, marker technologies, contract studies and project coordination. He is also a board member of the ABIC Foundation, Canada, and BioCologne eV, Germany.

Past Successes, Future Prospects and Hurdles

Session II Q&A

Moderator: Ralph W.F. Hardy
National Agricultural Biotechnology Council
Ithaca, NY

> *There is a black market in* Bt *cotton seed. And sometimes seed that is supposedly* Bt, *but is not, is being sold.*

Peggy Lemaux (University of California at Berkeley): For Vijay. I have two Indians in my lab and when the issue of problems with *Bt* cotton came up I asked them to find out what was going on. They mentioned, along with some other people, that there is a black market in *Bt* cotton seed. And sometimes seed that is supposedly *Bt*, but is not, is being sold. Can you either confirm or deny that?

K. Vijayaraghavan (Sathguru Management Consultants, India): Initially just one company, Mahyco, produced *Bt* cotton seeds in India, in a joint venture with Monsanto. But their ability to satisfy demand was limited. In the second and third years it was realized that they needed distribution across the country so they took a strategic decision to sub-license various companies that produced locally adapted hybrids for different regions. The price of a regular pack of seeds is about 400 rupees, whereas transgenic seed sold at about 1600 to 1700 rupees. This steep increase in price made it difficult for many small farmers to procure them. To satisfy demand for transgenic seed, "informally" crossed genotypes became available, But then they realized in the second and third seasons that some of the F2s were not performing well and there was huge disappointment. That's where the government intervened. There is a considerable social factor in this. You have farmers who can afford the seed and are able to increase their income many-fold. And you have a huge segment of farmers who have no access to transgenic seed because the public sector has not adopted any strategy to bring out transgenic seeds there. It's going to take a lot of time to convert them to hybrids. The affordability of hybrids can only be increased by increasing the credit to farmers. There are no data on "informal" seed adoption, so it's difficult to determine precisely to what extent it takes place; but there is considerable acreage with informal seed cultivation.

Steve Pueppke (Michigan State University): Ana, I was interested to hear you say that you can double the yield of ethanol from sugar cane by digesting and fermenting the fiber. Have you compared that yield to a process that converts the fiber to syn gas then the syn gas to ethanol?

Ana Claudia Rasera da Silva (Alellyx Applied Genomics, Brazil): The enzymatic process is best. One approach is to add enzymes to the bagasse, a second approach is to engineer the microorganism to digest the cellulose and the third is to put the enzyme inside the sugar cane such that when the cane is crushed the enzyme is released. We are still developing the technology to put the enzymes inside the plant.

Dalia Abbas (University of Minnesota): For Ana: how do higher sugar-cane yields affect soil nutrient status?

Da Silva: Actually it's not a problem at all because we just increased the capability of converting fibers to sugar. There is a balance between sugar and fibers, and in the energy cane you have more fibers than sugar. So there is no impact for the soil. And also for all the field trials that have been done in Brazil we have regulatory approval from the government.

Ralph Hardy: Can the panel offer guidance on aspects of industrial biotechnology that may produce problems similar to those that arose in food biotechnology?

Vijayaraghavan: From the Indian perspective, one area we have been heavily investing in, in the recent past, is the application of technologies for alternative fuels. There are several options for farmers to go with when talking about fuel from farm produce, fuel from non-farm produce, fuel from food produce, fuel from non-food produce. As of now, we don't have any clear scientific approach in accessing the economic compatibilities of these options. We may find a farmer growing tapioca then he gets to know that sorghum is better so he gets into sweet sorghum but then he gets to know that sugar cane is a better option and he jumps into sugar cane. We need to marry good economics with good science and say that these are the options that are worth exploring in these environments, rather than seeing science as an independent analysis. We need to entice investments with a clear economic analysis that reflects compatible application of science in different environments. That's essential when considering industrial applications.

One of the mistakes we should not repeat is to keep things secret.

Peter Welters (Phytowelt, Germany): One of the mistakes we should not repeat is to keep things secret. Industrial biotechnology people like to keep things secret where they are not forced to label their products. If they were forced to label, you would have labeling on nearly 70% of all of the processed food in Europe. Washing powders contain enzymes produced in genetically engineered microorganisms for cleaning of apple juice, also for bread baking and cheese making. Even organic food shops sell cheese produced with chymosin from genetically engineered microorganisms. I think we should tell the consumer where genetic engineering is already making positive contributions.

Hardy: I appreciate your comments.

Function and Role of University-Based Research Parks in Economic Development

From Tools to Products and Processes: The Evolution of Saskatchewan's Agricultural Biotechnology Cluster

Ashley O'Sullivan
Ag-West Bio Inc.
Saskatoon, SK

Saskatchewan is one of the three prairie provinces of Canada. Although the population is less than a million, it boasts 47% of Canada's arable land and is home to one of the largest and fastest-growing agricultural biotechnology clusters in the country (Lautermilch, 2002).

The core of the ag-biotech infrastructure is the University of Saskatchewan (U of S), the Agriculture and Agri-food Canada Research Centre (AAFC-SRC), the National Research Council's Plant Biotechnology Institute (NRC-PBI), and the Saskatchewan Research Council (SRC).

The U of S has five life-science colleges on campus:

- Western College of Veterinary Medicine,
- College of Pharmacy and Nutrition,
- College of Medicine,
- College of Agriculture, and
- College of Arts and Science.

The university has additional research capacity with the College of Engineering, as well as major institutions such as the Vaccine and Infectious Diseases Organization (VIDO) and the Canadian Light Source Synchrotron (CLS).

In 1977, the provincial government leased land from the University to establish Innovation Place.

In 1977, the provincial government leased land from the U of S to establish Innovation Place (Beggs, 2006), a research and development park immediately adjacent to the campus that currently:

- is home to 137 companies and agencies,
- has eighteen buildings and supporting infrastructure with over a million square feet of laboratory and office space,
- has a staff of 2,200, and
- contributes approximately $250 million/yr to the GDP of the province

Early Research Activity

The early focus of research activity in the community included:

- plant breeding, genetics, protection, nutrition,
  - cereals (wheat, barley, oats)
  - oilseeds (canola, flax)
  - pulses (peas, beans, lentils)
  - forages (grasses and legumes)
- animal health and nutrition,
  - beef, swine, poultry

With respect to crops research, the major emphasis was on the development of new varieties of commodities for food and feed applications as well as crop-production technologies.

Agricultural biotechnology was potentially a key driver of value for the agriculture sector. Ag-West Bio was established in 1988 by the province of Saskatchewan to provide leadership in the development of this sector.

In the 1980s, our science and political leaders—with great foresight—realized that the emerging science of agricultural biotechnology was potentially a key driver of value for the agriculture sector. Ag-West Bio was established in 1988 by the province of Saskatchewan to provide leadership in the development of this sector. During the period 1992–2002, more than $700 million were invested in the region's infrastructure (McCann, 2002).

Also in the 1980s, there was the realization that genes controlling economically important input traits, such as herbicide tolerance and insect resistance, that were under development—plus other emerging tools, *e.g.* plant-transformation protocols and increasing knowledge of the regulation of gene expression—when commercially introduced, would have a profound impact on the business of food production.

Success Stories

Saskatoon has had many ag-biotech success stories over the years, for example the development of novel vaccines by VIDO (VIDO Report, 2001) and a bloat-reducing alfalfa by Agriculture and Agri-Food Canada (Coulman *et al.*, 2000). However, the greatest economic impact came from the development of canola, now Canada's second most important crop. The canola story has been reviewed in detail by Phillips *et al.* (2001) and by Keith Downey in this volume[1]. With significant research work at NRC-PBI and AAFC-SRC, Saskatoon became the national centre of excellence for *Brassica* development. Considerable work was also done in collaboration with the University of Manitoba.

The NRC and AAFC laboratories had major R&D activity in breeding, molecular biology, chemistry, entomology, pathology and agronomy with strong teaching and research support from the U of S. As a result of this concentration of expertise, a number of multi-national companies moved components of their R&D programs to Saskatoon to be in proximity to the publicly funded infrastructure [scientific expertise, intellectual property (IP), facilities, equipment and money]. Strong public/private collaborations developed and public/private IP was bundled to create commercial products. The first commercial field-planting of a genetically engineered (glufosinate-resistant) canola crop occurred in 1995 (Bijman, 2001) as a result of the collaboration among AgrEvo-PGS, AAFC and NRC-PBI.

The Saskatchewan ag-biotech cluster was born.

And so, the Saskatchewan ag-biotech cluster was born. The reasons for the early success with respect to the canola example include:

- excellent scientists in public institutions with significant IP assets and a highly transformable, economically important crop (canola),
- provincial government foresight in establishing Innovation Place research and development park immediately adjacent to the U of S, and support for the establishment of Ag-West Bio in 1988,
- the concentration of institutions and scientists on the same campus and immediately adjacent research and development park (Innovation Place),
- the excellent communication, networking and spirit of cooperation among all of the players; and a "can-do" attitude,
- excellent infrastructure (laboratories, equipment and operating dollars),
- strong provincial and federal government support,

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[1]Pages 67–76.

- the potential for making money attracted multinational companies to locate some R&D capacity to Saskatoon [AgrEvo (Aventis, Bayer), Monsanto, Dow, DuPont/Pioneer, *etc*.], and
- successful commercial products in the marketplace with significant revenue potential.

Dynamic Clusters

Biotech clusters are not static; they are dynamic communities, constantly evolving. Our Saskatoon cluster is no different. The major opportunity for the cluster is to capitalize on our comparative advantages by identifying and pursuing opportunities at which we can be globally the best. In that regard, there are potentially huge opportunities in the emerging bio-economy.

So, what is the bio-economy? From the perspective of Ag-West Bio Inc. (AWB), the bio-economy simply involves creating and capturing value from "biological systems."

The oval in Fig. 1 represents the genetic code of a biological system (plant, animal or microbe). Many tools, such those listed on the left side of Fig. 1, have evolved over the years to create value in biological systems for humankind. They include everything from naturally occurring biological systems without any modification through to the use of modern biotechnology to modify the genetic code to create value, such as herbicide

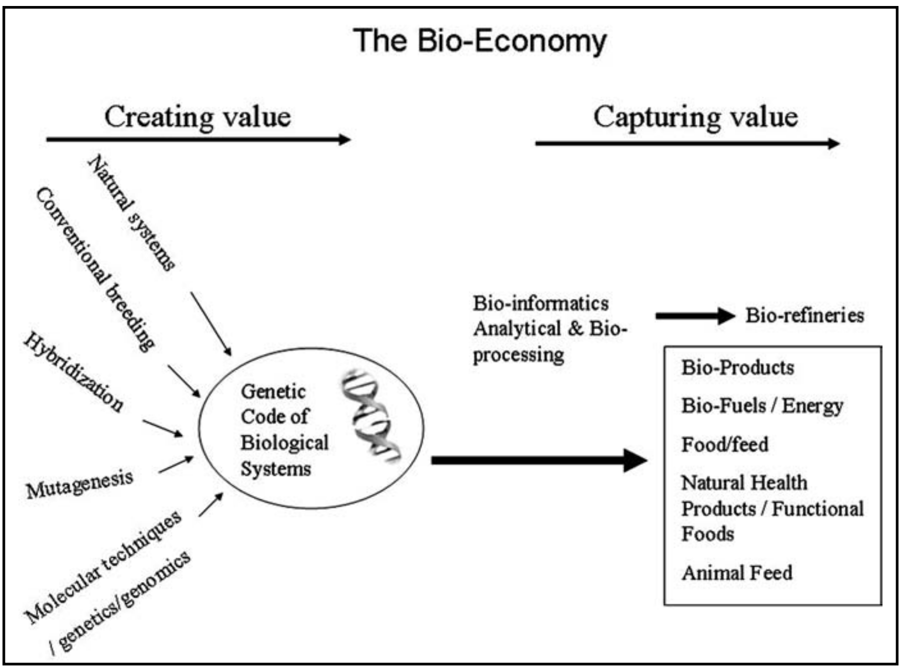

Figure 1. A schematic showing how value is created and captured in the emerging bio-economy.

tolerance in crops. After the research has been completed to create the value, advances in bio-informatics and analytical and bioprocessing technologies can be used to produce a range of products: from natural health products through to biofuels and bio-industrial platforms such as the corn-sugar based platforms [*e.g.* DuPont's 1,3 propanediol (PDO) (DuPont, 2000), ADM's polyhydroxyalkanoate (PHA) (Peterson, 2006), and Cargill's polylactic acid-PLA (Brady *et al.* 2005)].

Strategies and Strengths

The challenge and the opportunity for each region are the ability to understand and to effectively exploit global comparative advantage. Our strategy at Ag-West Bio for Saskatchewan is twofold:

- marketing our excellent bio-economic infrastructure, and
- identifying and targeting strategic opportunity sectors.

In terms of marketing the infrastructure globally, we promote ourselves as a solution-provider:

> Looking for reliable, quality ingredients, analytical or processing capabilities, innovative research, or a path to commercialization? From research to market, Saskatchewan offers the Solution!

We have an extensive list of assets throughout the full spectrum of the research-to-market value chain. These include a robust R&D capacity; analytical, bioprocessing and bio-informatics capacity; and support services and private industry. Examples of these assets include:

- **Research and development capacity**
  - *Environmental technologies*
    - Biological controls (weeds, insects and diseases)—U of S Department of Plant Sciences, AAFC-SRC, NRC-PBI, Saskatchewan Wheat Pool (SWP)
    - Biotic / Abiotic Stress Resistance—U of S Department of Plant Sciences, AAFC-SRC, NRC-PBI, SWP
    - Seed oil modification—U of S Departments of Plant Sciences and Chemical Engineering, AAFC-SRC, NRC-PBI
    - Plant Pathology—U of S Department of Plant Sciences, AAFC-SRC, NRC-PBI
  - *Bioenergy, bioproducts, renewable industrial feedstocks/biorefineries*
    - Bio-energy/fuels—U of S College of Agriculture and Chemical Engineering, Petroleum Technology Research Centre (PTRC)
    - Bioproducts—U of S Departments of Plant Sciences and Chemical Engineering, AAFC-SRC, NRC-PBI, SRC
    - Renewable feedstock platform—U of S, AAFC-SRC, NRC, SRC

- *Health and nutrition technologies*
  - Human health and nutrition—U of S Department of Microbiology & Food Science, Colleges of Nutrition & Pharmacy and Medicine
  - Animal health and nutrition—U of S Department of Animal & Poultry Science, College of Pharmacy & Nutrition, Western College of Veterinary Medicine (WCVM), VIDO, SRC

- **Analytical and bio-processing capacity**
  - Canadian Light Source Inc.
  - Innovation Place Bio-Processing Centre
  - Saskatchewan Research Council
  - Phenomenome Discoveries
  - Saskatchewan Food Industry Development Centre
- **Support services**
  - Greenhouse/field trials—AgQuest, ICMS, AAFC, Prairie Plant Systems, Innovation Place
  - Diagnostics—Phenomenome Discoveries, Bio-ID, Prairie Diagnostics, CFIA, Genserve, Bovacan
  - Funding—AWB, Foragen, Golden Opportunities, Agriculture Development Fund (ADF), NRC's industrial research assistance program (IRAP), Crown Investment Corporation (CIC), others
  - Economic development—AWB, Saskatoon Regional and Economic Development Authority (SREDA), Innovation Place, U of S Industry Liaison Office
- **Private-sector companies**
  - *Environmental technologies*
    - Inoculants—Philom Bios, Becker Underwood
    - Ag-Biotech—Bayer, Monsanto, BASF, Pioneer, Performance Plants, Syngene, Agrisoma, aDNAdvance
    - Biocontrol—Heads-up Plant Protectants, Peacock Industries
    - Organic waste digestor—Clear-Green Environmental
  - *Bioenergy, bioproducts, renewable industrial feedstocks/biorefineries*
    - Biomass energy—Zelensky's Saw Mill; Nipawin NewGen Co-op
    - Grain ethanol—Poundmaker, Noramera Energy, Husky, others planned
    - Fiber and composites—Biolin, Bio-Fibre Industries, Bio-Hemp Technologies, Hemptown
    - Biodiesel—Milligan BioTech, Saskatoon DSG

— *Health and nutrition technologies*
  - Feed—MCN Bioproducts, GNC BioFerm, Guardian Phenomenome, Bio-ID
  - Health and nutraceuticals—Bioriginal, Fytokem, Emerald Seeds, Infra-Ready, BioNatCom, Bio-Diagnostics, Phenomenome, Bio-ID

In considering our general areas of strength, we look at some of the current global economic drivers and consider how transitioning to a renewable bio-economy either solves problems or adds value in some way. Major global economic drivers that will be impacted by the transition to a bio-economy—where Saskatchewan can be a leader—are:

- energy
- health
- environment

In terms of bio-energy opportunities, Saskatchewan will be a major player in ethanol and biodiesel production. We also have the capacity to be a player in biogas and a biomass-based hydrogen economy.

With respect to the environment, our renewable fuels will contribute to reduced greenhouse-gas production. We will develop alternatives to petroleum-based feedstocks for the production of a range of industrial and consumer products. These will be carbohydrate- and oil-based platforms. And we will continue to introduce biological alternatives to pesticides and chemical fertilizers.

We will also be a major player in bringing Canada's healthcare system back from the brink. Currently, it is primarily a reactive system: one gets sick, goes to the doctor, gets some kind of intervention and gets well. When one looks at the skyrocketing cost of this system to our public treasuries and the age demographics of our population, clearly it is not sustainable. We believe that the future healthcare system will involve a shift to a more-balanced wellness model that will include better nutrition, better understanding of the relationship between the food that we eat and the benefit or disease that it may cause (nutrigenomics), diagnostic tools to understand disease predisposition, and the greater use of natural health products, nutraceuticals and functional foods. The Saskatchewan bio-economic cluster is well poised to exploit the agriculture- and nutrition-anchored wellness opportunity for the benefit of Canada.

Saskatchewan is evolving from a tool-based ag-biotech cluster to an outcome-based bio-economic cluster.

In Conclusion

Saskatchewan is evolving from a tool-based ag-biotech cluster to an outcome-based bio-economic cluster based on:

- global marketing of the infrastructure (Solutions), and
- becoming a global leader in specific strategic technology outcomes:
    - energy
    - health
    - environment

This is an extremely exciting time when agriculture and other renewable-resource-based sectors are undergoing transformational change. For agriculture, advances in science are creating opportunities for Saskatchewan to:

- develop innovative, environmentally sustainable production systems,
- reposition agriculture as part a wellness solution to the healthcare crisis in Canada,
- move towards energy security through the exploitation of biobased feedstocks,
- expand agriculture beyond traditional food and feed to include biobased renewable feedstock platforms for the production of industrial and consumer products, bio-composites, natural health products, biochemicals and biopharmaceuticals, and
- facilitate the development of a number of biorefineries to maximize economic impact.

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As president and CEO of Ag-West Bio, **ASHLEY O'SULLIVAN** is responsible for working with the board of directors to establish the strategic direction and focus for Ag-West Bio in support of the growth of the bio-economic sector in Saskatchewan.

Born in Cork City, Ireland, he completed a BSc and PhD at the University College Cork before moving to Canada in 1973 for a research associate position at the University of Alberta in the Plant Sciences Department. At Monsanto Canada he was responsible for R&D in Western Canada. In 1978, Dr. O'Sullivan joined the team at Agriculture Canada and served as research head at the Lacombe Research Station; assistant director at the Lethbridge Research Station; Director of the Swift Current Research Station; and director of the Saskatoon Research Centre.

While with Agriculture and Agri-Food Canada, he obtained a wealth of international experience as the Canadian principal advisor for the India Dryland Project in Hyderabad; managing a CIDA-sponsored research project at Rio Grande do Sul, Brazil; and as research advisor to the Hebei Dryland Project in China.

O'Sullivan also spent a year as the managing director of CABI Bioscience in the United Kingdom and has served on a number of management boards and advisory committees.

From Equines to Economic Development: The Story of the University Research Park

Allen J. Dines
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The story of the University Research Park in Madison provides an instructive case study of how favorable outcomes can arise from university-established parks focused on fostering commercialization of university research.

It is widely understood and even expected that commercialization of research coming out of university research laboratories should make strong positive contributions to economic development (*e.g.* Fischer, 2005; Palmintera, 2005). Moreover university-associated research parks, where they provide a favorable environment for research commercialization and growth and development of small companies spun out from university research, are often net contributors to the economy of their regions while serving to foster the university's role of service and outreach. The story of the University Research Park (URP or "the Park") in Madison provides an instructive case study of how favorable outcomes can arise from university-established parks focused on fostering commercialization of university research.

The operant word in the term "University Research Park" is *university*. Without its affiliation with UW-Madison, URP would be just another modern office park that may or may not house technologically innovative companies or companies focused on developing novel, cutting-edge products. Research parks can and do exist without the involvement of a university but close proximity to, and association with, a research university greatly enhances potential for local economic growth while serving to enhance the development of emerging young companies that take up residence within the park.

Before moving to specifics of the UW-Madison and the URP, we need to back up several steps to place the story in a twenty-first century economic development context. We live in a knowledge economy and it is commonly understood that the first step in the path to economic growth is new knowledge. For convenience, we borrow here from a characterization drawn from a publication of the Wisconsin Technology Council in its *Vision 2020* plan for growth for the high-tech economy in Wisconsin (Wisconsin Technology Council, 2002). In that report, the path from knowledge to growth included four major steps:

- New knowledge. Otherwise known as technology or more simply put: know-how. New knowledge is the raw material that drives the subsequent steps. It is the ability to do something—usually something that had not been done before, or not done before as quickly or cheaply.
- Technology innovation. The key next step is the application of the knowledge to a practical problem to create a new and novel way of doing something.
- Competitive advantage. Competitive advantage is added to the mix when an innovation uniquely solves a problem better than other prior or current approaches. Implicit with competitive advantage is the understanding that someone is willing to pay to have access to this new innovative solution.
- Economic growth. This is the end-point of technological innovation. It is where the three preceding components come together to enable the growth of a sustainable business that expands the workforce, generates income for employees and wealth for investors.

New knowledge can come from anywhere. Similarly, technology innovation can arise from anywhere independent of the source of the new knowledge. But universities are fundamentally in the knowledge business. They transfer knowledge (primarily in the form of graduates from varied degree programs) and they create knowledge (in the form of research). Thus, it is not surprising that universities, particularly research universities, are associated with regions having strong economic growth.

The Essential University

Let us take the idea that today universities and economic development are, in fact, closely linked and go a step further. If we think about what a university is, it tends to be in terms of observable characteristic phenomena. For example, a university might be thought of as a collection of facilities—classroom buildings, lecture halls, laboratories, sports facilities, arts facilities, housing for students and offices for faculty and staff. On top of that view, we might layer a vision of a university in terms of its academics—a collection of programs related to degrees conferred, curricula, courses, the myriad academic departments that dispense teaching and learning. A university might also be understood in terms of its people—the faculty, students, staff and visiting scholars. For those in the research-associated fields, a university may even be thought of in terms of its research capabilities, its research accomplishments, its intellectual property and centers and institutes.

In light of our topic about the link between universities and economic growth, I suggest a different approach about how to conceptualize a university. It can be thought of as a community where bright people come together to exchange ideas. In this view, the essence of a university is its role as a center to facilitate the free flow of ideas—a center where ideas are born and exchanged. In a knowledge economy, this phenomenon takes on special importance. The collective creative energies of actively inquisitive people associated with the university community generate new knowledge. That new knowledge, when channeled or facilitated by appropriate institutions, flows as a benefit to the local community and to society at large. The quantity and quality of the new knowledge generated is a function of the diversity of talent and expertise associated with the multiple schools and colleges that populate the campus. A great university is not just the sum total of the capabilities of its faculty staff and students in its component colleges. What distinguishes a great university is the synergistic excellence that occurs as a result of the co-location and cross-fertilization of so many talented and inquisitive people. One could argue that the broader the representation of disciplines housed at a university and the greater their skills, the greater will be the potential for creation of new knowledge.

This is important because innovations—the novel integration of new ways of thinking about "what we do" and "how we do"—are integral to growth in the twenty-first century economy. Therefore, universities—particularly research universities—are significant generators of new knowledge in an era in which innovation and incorporation of new ideas into business and industry are key to growth of the economy.

Then, if a university is in essence a place where people come together to exchange and create ideas, then how does one move from the knowledge to the economic growth? In other words, what of those other steps? The conventional view is that universities offer access to research and new knowledge. But that ignores the other steps needed to produce those economic gains. Universities indeed generate new knowledge and provide access to their research through tech transfer. But new knowledge is not simply something that can be harvested like a ripe peach picked from a tree. New knowledge requires the addition of innovation and creation of competitive advantage to fulfill its potential. The value of a great university is that the convergence of open and inquisitive minds typical of that environment serves as a magnet to draw other creative types seeking high-energy settings that are open and creativity-friendly. These environments span the arts, culture as well as science and they involve entrepreneurs and others who seek opportunities in novel ideas.

The story of any university-affiliated park is inherently tied closely to the resources, capabilities and culture of its affiliated university.

UW-Madison Snapshot

My first major point is that the university is a key part of a university research park and the story of any university-affiliated park is inherently tied closely to the resources, capabilities and culture of its affiliated university.

As one of the nation's premiere universities, the University of Wisconsin-Madison fits perfectly the above described model of a university community as a magnet for ideas. UW-Madison offers a broad array of human and educational resources that serve to enrich the immediate surrounding community, in this case the city of Madison and the other cities and towns that comprise the greater Madison area. The tremendous research advances and business resources originating from UW-Madison benefit the local and regional economies, impact business development in the state, and provide an ever-growing base of knowledge and human capital to Wisconsin. A recent economic study found that the UW-Madison has a $4.7 billion economic contribution to the regional economy (Winters, 2002). To provide an understanding of the size and scope of the UW-Madison as a major institution of higher learning and as a contributor to innovation and technology commercialization, consider the following:

- UW-Madison is ranked as seventh best public university in the United States (2004)
- More than forty UW-Madison academic programs are ranked in the top ten (2005)
- 2005 total student enrollment was 41,480
  - Undergraduate: 28,458
  - Graduate: 8,841
  - Professional: 2,533
  - Special students: 1,648
- UW-Madison consistently ranks in the top five nationally on doctorates conferred; Harvard ties UW-Madison in having fifteen grads as CEOs of S&P 500 companies, according to *Bloomberg Markets Magazine*.

The University of Wisconsin-Madison ranks fourth among research institutions nationally according to 2005 figures available from the National Science Foundation, with $721 million in R&D spending. UW-Madison has been engaged in research for a long time and key accomplishments over the past 100 years include:

- First test of butterfat content in milk (1890)
- Discovery of vitamin A (1913), vitamin B (1916) and methods to enrich food with vitamin D (1924)
- Methods to iodize salt (1930s)
- Blood anticoagulants (coumarol, Warfarin) (1952)
- First bone marrow transplant (1968)
- Creation of the first synthetic gene (1970)
- Vitamin D derivatives (1971)
- Nation's first on-campus blood-donation center (1973)
- MRI imaging technology (1985)

- Organ transplant solution, used in transplant surgery (1989)
- Vitamin D analogues (1990s)
- Human embryonic stem cells (1998)

The university continues to build on its research excellence. In early 2006, it announced additional commitment of $150 million, with $50 million each from the Wisconsin Alumni Research Foundation (WARF), the state of Wisconsin and UW-Madison alumni John and Tashia Morgridge, for the creation of the Wisconsin Institutes for Discovery, a public-private research partnership. The private side of this partnership is the establishment of the Morgridge Institute for Research modeled on successful research centers on the east and west coasts, such as the Whitehead Institute at MIT and the Clark Center at Stanford.

A frequent Schramm thesis is that many university innovations are either mired in outdated and inefficient policies or are paralyzed by lack of skills and resources needed to apply them.

In an opinion column by Carl Schramm, President of the Ewing Marion Kauffman Foundation, UW-Madison was named as one of the top-five universities in the United States for its ability to work proactively with industry (Schramm, 2005). This is significant because a frequent Schramm thesis is that many university innovations are either mired in outdated and inefficient policies or are paralyzed by lack of skills and resources needed to apply them.

UW-Madison has also been long active in generating spinout companies based on university research and innovation. UW-Madison technology commercialization has resulted in formation of more than 218 new companies with connections to the university. One hundred and fourteen of these are direct spin-offs due to UW research, 104 are located in the City of Madison, which collectively generate more than $1 billion in gross revenues and employ 6,700 people.

Technology transfer and commercialization at UW-Madison rests with three organizations:

- WARF
- OCR (Office of Corporate Relations)
- URP

The Office of Corporate Relations is the front door to the university for business and industry, helping companies access those university resources that can make a difference in building their businesses and strengthening their competitiveness. It is organized within the chancellor's office, therefore its operational scope is campus-wide, and it serves principally to connect business and industry with resources of the university in the following areas:

- Graduate recruitment
- Intern placement
- Continuing education and professional development
- Assistance from faculty experts, sponsored research
- Access to research centers and consortia
- Assistance with International business issues and global markets
- Transferring technology to the private sector

The Office of Corporate Relations maintains a targeted communications program to strengthen recognition of the university by business and industry. Its mission also includes fostering growth of startup businesses based on university research. Through its New Business Startup Initiative, OCR works with nascent and emerging spinouts from the UW-Madison to assist in their growth and development.

The Wisconsin Alumni Research Foundation patents the discoveries of UW-Madison researchers and licenses these technologies to leading companies in Wisconsin, the United States and worldwide. Through licensing, WARF facilitates the use of UW-Madison research for the maximum benefit of society, business and industry.

Unlike many university technology-transfer offices, WARF is an independent not-for-profit foundation. Thus, it is entirely separate from the university and is not an organizational entity of state government. Founded by UW alumni in 1925, WARF operates with the express purpose of benefiting research at UW-Madison and ranks in the top ten nationally on technology-transfer metrics almost every year. Currently, it makes royalty distributions to more than 300 faculty researchers. Beyond payments of inventor's share of royalty proceeds, WARF's annual gift to UW-Madison for the last several years has been in the $40–55 million range.

The Wisconsin Alumni Research Foundation operates with a staff of fifty and maintains a west coast satellite office in order to be closer to its customer base, which is substantially located in California's life science sector. In 2005, WARF was awarded the National Medal of Technology, the nation's highest honor in recognition of achievements in technology and innovation.

A university-affiliated research park is an excellent tool to facilitate the journey from new knowledge to economic development.

The University Research Park

My second main point is that a university-affiliated research park is an excellent tool to facilitate the journey from new knowledge to economic development. The URP is an internationally respected research and technology park, the approach and innovative tenant solutions of which help encourage development and commercialization of new ideas.

The URP's mission is to encourage technology development and commercialization that advances the economy and benefits research and educational programs at UW-Madison. In fulfilling this mission, the Park serves to provide the physical lab and office space where faculty- and staff-based start-up ventures can take root and grow. In supporting this entrepreneurial activity, the Park is creating and building an asset for the UW-Madison, stimulating growth of high-tech jobs in the Madison community and serving as a recruitment and retention tool for UW-Madison faculty.

Founded in 1984, the Park was more than 20 years in the making and the subject of considerable debate by university leaders (Hove, 2006). It is built on former university research land. The equines referred to in the title of this paper roamed the pastures that are now the Park. A small number of horses remain on the site today as part of a facility run by the UW School of Veterinary Medicine. Tenants in the Park must have some relationship with the UW-Madison and rents have always been at market rates. Strict building standards and green-space minimums are in place to assure that the Park remains an aesthetically attractive part of the City of Madison. Developments in the Park are limited to research facilities and corporate offices with no commercial or retail development. The Park is managed by a wholly separate 501 c (3) corporation. Although the URP, Inc., is an entity separate from the university, its staff members are university employees.

Today the Park's 255 acres are more than 90% built out with similarly high occupancy. Some 1.5 million square feet of space are under roof in thirty-four buildings, about half of which are owned by the Park. The Park pays $3.5 million per year in property taxes to the City of Madison based on assessed valuation of the properties of more than $160 million. The Park's 114 tenant companies employ more than 4,000 with an annual payroll of nearly $260 million.

Because a key part of the Park's mission is the encouragement of commercialization of technology, significant effort has gone into the development of the Madison Gas and Electric (MG&E) Innovation Center as the centerpiece of the Park. The local electric and gas utility provided significant initial capital to build what has now grown to a 113,000 square-foot facility providing wet-lab and office space, support equipment and personnel to tenant companies. The initial Innovation Center was opened in 1989 in an early Park building with just 10,000 square feet. The current MG&E Innovation Center, now housed in its own building, opened in 1999 at more than 50,000 square feet and doubled in size 2 years later. The Center is 100% occupied, with forty companies in eighty-five incubator suites. Amenities include:

- UW Library access
- DS-3 data connection
- Nine conference rooms
- Dining commons
- Admin support
- 24-hour access
- Shared lab equipment

- Storage
- Machine shop
- Small animal facility

The early growth and success of the URP have led to the development of a Phase 2 location in Madison, which will provide over fifty building sites on 270 acres. The new site, 3 miles west of the Park, is also on land owned by UW-Madison and formerly used for agricultural research. When fully developed URP-2 will be home to more than 200 tenant companies with estimated employment of 10,000–15,000.

Conclusion

With more than 20 years of operating history, the Park has met its objectives in virtually every respect. In terms of economic development, several of the tenant companies of the MG&E Innovation Center have grown and moved on to occupy their own buildings in the Park or have moved to other larger facilities elsewhere in the Madison area. These include Third Wave Technologies, Tetrionics (now owned by Sigma Aldrich), Pan Vera, (now owned by Invitrogen), Novagen (now owned by EMD Biosciences) and Epic Systems. The Park's role in providing the physical facilities for startup companies to grow has served to foster commercialization of UW-Madison research while providing a recruitment tool to attract new faculty. The growth of value of the Park properties themselves has created a vastly greater asset for the UW-Madison. Cash flows from Park operations are just beginning to enable URP to make dividend payments back to UW-Madison to support research, much in the same way WARF has made annual gifts for years from its operations to support research at the university.

More importantly, the Park has had a broad impact on the area as a whole by helping to grow Madison's biotechnology industry and by contributing to the high-technology cluster that has emerged. In 2004, *Forbes Magazine* called Madison a "Hot-bed of Bio-capitalism" in its annual review of best cities for business (Badenhausen, 2004). That year, Madison was named the number-one city under 500,000 population as a place in which to do business. During the initial years of operation of the Park, tenants were typically spinouts from the university. Recently, the Park has come to the attention of companies interested in relocating to the Madison area because of the high profile of the university and the opportunities of being associated with the university research environment. Although the Park remains the single largest concentration of high-tech companies in the Madison area, the region is showing its growth and viability in that several other centers of high-tech company concentration are emerging there.

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Allen Dines is assistant director of the University of Wisconsin-Madison Office of Corporate Relations (OCR). Operating within the Office of the Chancellor, the Corporate Relations office assists the business community in accessing the diverse resources of the university. As assistant director, he also serves as program manager for the UW-Madison New Business Startup Initiative. He is broadly involved in outreach to business and industry, promoting local and regional economic growth through commercialization of research and fostering cooperative relationships for UW-Madison in Wisconsin and beyond.

Mr. Dines joined the UW-Madison in June 2001, bringing with him more than 25 years of experience in industry and technology management. In his initial position as assistant director for business development within the graduate school, he served as a "faculty coach" for university-based startups. In 2002, he co-founded the Midwest Research University Network (MRUN), an alliance of twenty-two midwest research institutions dedicated to regional cooperation in the commercialization of university research through new business creation. Currently he serves as president of MRUN. He also serves on advisory boards of Urban Technology Catalyst, Candela Solutions, LLC, the AEISEC Madison Chapter and the UW-Madison Entrepreneurship Association.

Dines holds degrees from the University of Michigan including a BS, an MBA, and a Masters in Natural Resources.

Food for Innovation: The Food Valley Experience

WIM M.F. JONGEN
Wageningen Business Generator
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For hundreds of years, universities in the various European countries have been *the* place to be for scientific developments. Science developed in an independent manner and research was financed by the respective governments supplemented with money from special funding bodies. The primary aim was to further the various scientific disciplines, to ensure that scientific knowledge was made available for colleagues and the public at large, and to educate and train students in thorough scientific methodology. All of this was almost totally separated from general economic development.

Development of the sciences has been extremely successful and scientific discoveries now form the foundation of economical development such as in the fields of chemistry, pharmaceuticals and biotechnology, and, more recently, in the food area. The latter has presented universities with a new challenge, which in the European context has been termed the "knowledge paradox": developed knowledge cannot necessarily be put to work.

The question is how to combine the general task of informing society of relevant scientific developments with applications for specific economic benefit. This has resulted in debate of whether universities should "go commercial" and, if they do, whether they still can fulfill their societal role adequately. In my view, these elements should not be considered contradictory but complementary. In many areas in which science plays a crucial role in economic development, the only way to create value from research findings is to bring them into an economic context by protecting them as intellectual property (IP). To develop an idea into a commercial product usually requires significant investment, which will be made by a company only if it creates specific commercial advantage such as a monopoly. Consequently, IP formulation and technology transfer are crucial to the achievement of societal benefits, through licensing patents. Additionally, there are findings that will not be picked up by existing companies because the economical risk profile is too high or the business fit is insufficient. These findings can result in the establishment of spin-out companies that create the desired value. Universities can and should be actively engaged in such developments as part of their societal role.

Food Valley is an example of regional-cluster development. Originating from an initiative on the part of three local city councils, it has developed into a leading regional economic force as a result of collaborations with a clear thematic focus.

Food Valley as a Concept of Thematic Regional Networking

If we accept that science-based economic development is crucial for general economic development and competitiveness, then the question arises as to how to organize these processes. Food Valley, developed in the Netherlands, is an example of regional-cluster development. Originating from an initiative on the part of three local city councils, it has developed into a leading regional economic force as a result of collaborations with a clear thematic focus.

Food Valley is needed for a number of reasons:

- To create a network for innovation and business
- To provide solutions for the knowledge paradox
- To create flexible responses to changing market dynamics
- To develop new markets for knowledge application
- To create new jobs

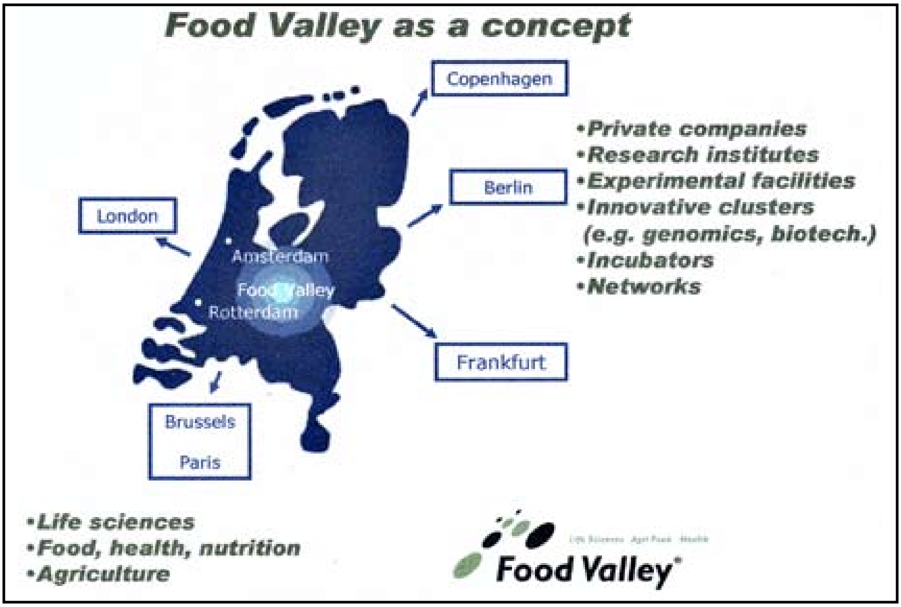

Figure 1. Food Valley as a regional concept.

The agri-food complex is an important economic pillar of the Dutch economy and the aim of Food Valley is the creation of a network for innovation and business involving companies, research institutes, experimental facilities, incubators and public-private-partnership based R&D programs. The focus is on food, health and nutrition.

The Food Valley organization consists of a small office and a consortium of more than sixty companies that participate in collective activities. The organization set itself the following targets for the first 4 years:

- To attract three major R&D centers to the area
- To establish twenty-five R&D-based companies
- To create twenty-five new innovative R&D projects
- To create 500–800 new jobs

Wageningen UR as a Leading Carrier for Development

Food Valley is in Wageningen at the same location as the offices and laboratories of Wageningen University and Research Center (Wageningen UR). Wageningen UR, which provides education and generates knowledge in the fields of life sciences and natural resources, is a collaborative entity involving Wageningen University, the Van Hall-Larenstein Polytechnic and specialized research institutes belonging to the DLO foundation, formerly under the Ministry of Agriculture. This combination of knowledge and experience has a staff of 6,500, a student body of 9,000 students and 86, 500 alumni.

Wageningen UR is a leading European academic and contract research organization. Among the top three in the worldwide publication index in the field of agriculture, it comprises:

- Research
  - Agriculture/food-wide portfolio of expertise
  - The continuum from academic to applied research
- Education
  - University (BSc, MSc)
  - Graduate schools (PhD)
  - Polytechnic institute
  - Business School for Life Long Learning
  - Wageningen International, for international products and services
- Commercialization
  - Research Institutes for Industrial Contract Research
  - Wageningen International for institutional collaboration and capacity building
  - Wageningen Business Generator for IP and spin-out companies

Its central mission is *To explore the potential of nature, to improve the quality of life.*

In general, the ways in which scientific developments are commercialized can be characterized by a number of features that add up to the so-called "Wageningen approach." A basic element is that complex problems are addressed using a systems approach. Wageningen UR's objective is to impact economic development via research and education in the life sciences. Innovation is key. A basic feature of many R&D programs is that technological aspects are studied in their societal context to provide not only solutions that work but also insight into the possibilities and/or limitations for implementation of new findings.

Wageningen UR policy includes being open to strategic alliances within Europe and globally.

New initiatives in Food Valley: The Framework of PPPs

The networks of dedicated players within Food Valley and Wageningen UR recently have resulted in a number of new activities, such as the Wageningen Center of Food Sciences (WCFS), a virtual research institute. The WCFS has been selected as a focal area for increasing the competitiveness of the Dutch economy. Financed by a conglomerate of industries, the government and research institutes, with an annual budget of €25 million, it carries out a selective number of so-called "pre-competitive" research programs.

Comparable initiatives are underway in the areas of biobased technology, bio-nano technology and green genetics. In addition, the government has established a total of five genomics-based research programs, two of which are under the auspices of Food Valley, namely Nutrition Biology and Systems Biology. A characteristic of all of these activities is that industrial participation is a prerequisite, not only intellectually but also financially: public-private partnerships (PPPs). Thus, strong foundations are laid for future innovations.

A characteristic of all of these activities is that industrial participation is a prerequisite, not only intellectually but also financially: public-private partnerships (PPPs).

Pre-Seed Activities: Making Science Work

One vital element in connecting science and the economy is the question, "How can we make science work?" Of course, an important element is that through intensive collaboration between existing industries and research institutes, the chances for innovation are increased and that the translation of science into products that can serve the market is taken up by companies. However, they will do so only if the product matches with their business plans and if the financial risk profile of the product is acceptable. In practice, a large number of potential opportunities are not explored and additional activities would be required to justify their exploitation. In addition, within the research environment in general, ideas are developed on the basis of individual activities that merit further exploration.

In general, academic researchers lack experience in translating ideas into products. This type of R&D requires a specialized environment. One advantage of Wageningen UR is extensive experience in industrial R&D within its research institutes.

The development of new spin-out activities from academic research within Europe has stagnated in recent years. One important reason is unfavorable risk profiles for investors who consider these early-stage developments. For example, the promises of early biotech developments have simply not been fulfilled; appropriate analyses of the chances of successful product development were lacking. Specific technologies were too immature to predict successful product development. Early-stage investors had no way of judging the state of affairs appropriately. On the other hand, the current situation provides opportunities for universities and research institutes. In principle, they can develop—or sometimes already have in place—the skills to become technological partners for investors. In future, partnerships between academia and early-stage investors may result in spin-out companies with greater potential for success.

Food Valley Consortium for Pre-Seed Activities

Within the Food Valley community, a consortium of partners for pre-seed loans has been set up to address these questions and to provide an environment that stimulates and facilitates commercialization. The consortium has selected a number of starting points for its work:

- Bring initiatives together to create synergy
- Unify patent policy and spin-out policy
- Provide a professional business environment with IP and legal expertise
- Operate independently and be able to say no
- Have adequate risk management
- Provide good funding capacity for pre-seed activities
- Be a professional technology partner for investors

Wageningen Business Generator has taken the initiative in setting up a consortium together with Oost NV, our regional development agency, the Food Valley Foundation and the Biopartner Center, our incubator. The aim is to build a sustainable structure that offers potential start-ups the means of developing ideas into commercial products.

The Wageningen Business Generator was set up by the board of Wageningen UR to create an environment for conversion of knowledge into commercially viable products.

Wageningen Business Generator for Pre-Seed Developments

The Wageningen Business Generator (WBG) was set up by the board of Wageningen UR to create an environment for conversion of knowledge into commercially viable products. It operates independently and creates economic value from science in the agri-food domain by identifying and selecting ideas with business potential, guiding them to the market place. In other words: making science work.

The WBG consists of a small team of domain-specific investment managers responsible for scouting and screening ideas and inventions that have business potential. At the same time, the investors are responsible for IP development at two levels. Operationally they assist in IP formulation based on ongoing research, the regular technology-transfer work. Strategically they work on IP development in a selected domain to build technology platforms. Also, WBG can provide expertise in legal and financial matters.

Annually, WBG aims to set up three to six new companies based on discoveries and findings from research within Wageningen UR.

Target Groups of the Consortium

The activities of the Food Valley Consortium have a regional focus, targeting two groups

- Inside Out—Spin-out activities from academic research, contract-research organizations and companies
- Outside In—Individual techno-starters within the agri-food domain unconnected to a Food-Valley organization

And services include:

- Coaching—To create successful spin-out companies neophytes are connected with experienced business coaches for advice and support
- Finance—Pre-seed loans are available to entrepreneurs who have the ambition to translate a business opportunity into a business plan, up to €300,000
- Facilities—Wageningen UR provides access to almost every kind of equipment, with housing infrastructure made available at reduced fees
- Patenting—Professional assistance is available for development of adequate IP positions in the agri-food domain.

From Science Via Skill to Profit: The Process

Figure 2 provides a schematic of the process. It is important to note that, at various stages, independent expert judgment is brought to bear, to determine whether the situation is "go" or "no go": at the level of the business challenge, at the start of the business case and at the start of the company.

When a business opportunity is screened, the project team makes an intake analysis. Following a positive decision, a "business challenge" is made. The initiator has to organize a team to prepare and participate in the business challenge and to prepare the plan, taking into account the technology, market, business model, benchmark, *etc*.

For the business challenge, which is a 1-day session, each team is assigned an expert to help explore their idea or invention; other experts are available for consultation in specific areas such as IP, financial aspects, *etc*. Each part of the session closes with presentation of

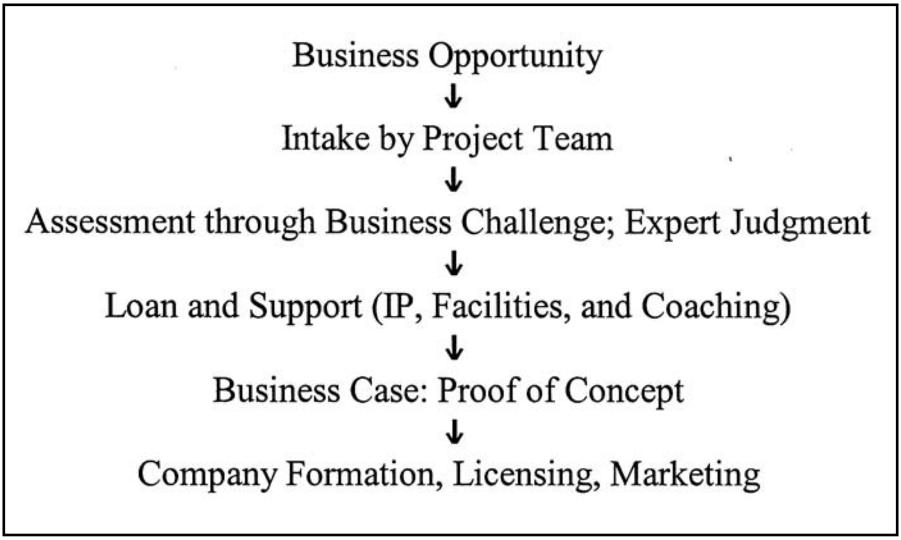

Figure 2. A schematic of the commercialization process.

the result. At the end of the entire session, the experts evaluate their findings and observations. Their opinion forms the basis for the selection process.

The business case is that part of the process in which the initiators have to achieve "proof of concept" (business development) for the product they want to put on the market. That can be an R&D period—maximum of 18 months—the establishment of an appropriate IP position, in general whatever is needed to reach the stage of proof of concept. At the same time they have to write a business plan that can be presented to investors. This approach increases the chances for successful spin-out companies: *Quality above Quantity.*

The Pipeline and Some Experiences

The Food Valley Consortium initiated activities early in 2006; so far, fourteen business proposals have been received, ranging from production of industrial oils from plants through molecular diagnostics for fresh produce to mucosal application of multivalent vaccines. This confirms that the agri-food pipeline is very good source of spin-out companies.

The "proof of concept" approach works well, and it has become clear that it is attractive to investors. Many informal investors and regional development agencies value the concept of a technology partner willing to invest. Generally, with better economic prospects, it seems that the investment climate is improving.

The Food Valley concept stimulates the development of an entrepreneurial climate and regional developments in general, primarily because it is organized around a theme and its activities are recognizable and transparent for possible business partners. It certainly helps that Food Valley wants to be a leader for Europe as a whole, within the agri-food domain.

Several lessons have already been learned:

- **Be patient: it takes 5–7 years to build a company**
  - Managers have to realize that success from these activities takes time. Return On lnvestment (ROI) is, of course, a prerequisite, but it can take longer than the longevity of the average manager.
- **To make money you have to invest money**
  - Tech-transfer offices are in operation in many European universities; their success is often hampered by lack of investment funds.
- **Build trust among scientists**
  - In academia, success is often defined by the quality of research dictated by a group leader. In the process of commercialization release of control is often necessary; it is of vital importance that the scientist(s) responsible for the original discovery or invention trust(s) the organization.
- **Create a professional environment for business development (proof of concept)**
  - Further to the previous lesson, trust is built by creating a professional environment in which targets are met, with good communication between scientists and administration.

For business creation, market potential is the deciding factor, not problem solving.

- **Be rigorous in decision-making**
  - Communicating a "no go" is always difficult; it causes disappointment and frustration, not least because scientists are trained to be creative in finding solutions for problems as they arise. However, for business creation, market potential is the deciding factor, not problem solving.
- **Partnering helps**
  - Input from external industrial experts for coaching and evaluating the business-creation processes and results is crucial. They introduce relevant experience and alternative perspectives into the process.
- **Regional support is most helpful**
  - The networking approach, part of the regional concept, is very useful. Innovations are rarely created in someone's attic; they result usually from multi-disciplinary interactions.

Further Reading

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Wim Jongen began his career as a technician at the former Institute for Insecticide Research in Wageningen, Holland, in 1972. In January 1975, he moved to the Toxicology Department of Wageningen University where he became an assistant professor in 1985. He obtained his PhD in 1988 and took a postdoctoral position at the International Agency for Research on Cancer in Lyon, France.

At the 1990 founding of the Agrotechnological Research Institute (ATO-DLO) in Wageningen, Dr. Jongen became head of the Post Harvest and Product Quality division and in 1994 was appointed professor of Integrated Food Technology. In 1999 he became professor of Product Design and Quality Management while serving as research director of ATO-DLO.

In 2001 he was appointed director of Business Development in the Animal Science Group, responsible for contract research, the IP portfolio and spin-off companies. Since January 2005 he has served as director of the Wageningen Business Generator, an affiliate of Wageningen University, responsible for development of the corporate IP portfolio and maximizing the impact of research through building business ventures. He also acts as chairman of the board of the Food Valley Group for pre-seed activities in building business ventures.

Innovation: The Chinese Experience

Zhanglian Chen
China Agricultural University
Beijing, China

The Chinese view of university-based research parks contrasts with what is happening in the United States and in Europe. When I returned from America after receiving my PhD from Washington University, I became a professor at Beijing University and later department chair and then vice president. For 7 years as VP, I was in charge of business development and ours became the largest university in China—possibly in the world—for such enterprises. Visitors to Beijing University are surprised to see that the scope of the business enterprises we run. They are not spin-off companies; they belong to the university.

High Tech Defined

The Chinese government has delineated eight high-tech areas:

- information technology,
- biotechnology,
- space,
- lasers,
- automation,
- new materials,
- new energy and
- ocean technology.

The strategy for promoting these high-tech areas was borrowed from Silicon Valley and Route 128 around Boston, and later Triangle Park in North Carolina. The effort was initiated in 1991, when government investment was significantly increased and domestic and foreign (United States) venture capital was sought to encourage new businesses. Tax preferences was instituted: high-tech companies pay no tax for 3 years, then 50% tax for the following 5 years. And new policies were instituted to attract talent from the United States, including entrepreneurs.

The Chinese government has, since 1991, encouraged university professors to form and run their own companies.

Professors as CEOs

The most important aspect of the strategy is that the Chinese government has, since 1991, encouraged university professors to form and run their own companies. Even in public universities, a professor can own shares, act as CEO or chair of the board and run a company using her/his own lab technology. This is very different from the situations in Japan and the United States—the Chinese government has gone significantly further than the US Bayh-Dole Act.

Our model is similar to the relationship that Stanford University has with Silicon Valley—from which we learned a great deal—using campus land for high-tech company infrastructure and receiving profits for reinvestment.

In 1999, the government granted building permission for the first university-associated science park. Since then, fifty have been constructed.

Beijing University Park

Plans were initiated in 1992 when I was a department chair and dean. The college received RMB400,000 (US$400,000 in purchasing power) from the university to form a high-tech company. The company groups formed included the Founder Group, which now controls 92% of newspaper printing technology; the Weiming Group is one of the largest biotechnology companies in the country; and the Science Park Group. The total assets of the Beijing University Enterprise stand at US$3.5 billion.

Six companies controlled by the Chinese Agricultural University are now listed in the stock-market, three in Hong Kong and three on mainland China.

Six companies controlled by the Chinese Agricultural University are now listed in the stock-market, three in Hong Kong and three on mainland China, in both Shenzhen and Shanghai. Revenue started to accrue in 1998 with US$900 million; the total was $3 billion at the end of 2005. This rapid financial success was not expected. The businesses run the gamut from computer chips to recombinant DNA.

I formed a company in 1992, using recombinant DNA technology to produce interferon-alpha 1b. This drug was chosen as treatment for hepatitis C, which is a particular problem in China, and this was the first company to produce interferon-alpha 1b domestically. In addition to being department chair and dean of the college, I was CEO and chairman of the board and the company developed rapidly and soon was the main producer in China of interferon-alpha 1b. We obtained investments from Hambrecht & Quist, San Francisco, of about US$20 million. It is a joint venture: we have a 51% share and they 49%. We are still the largest producer of interferon-alpha 1b in China. As it is such a large operation, we have come in for some criticism as a public university company.

Xinghua and the Chinese Agricultural Universities

China's second largest university, Xinghua University, had business revenues totaling RMB2.8 billion in 2004. I am now the president of the Chinese Agricultural University, and we have about twenty-five companies. One is listed in the Shenzhen stock-market. We have two major businesses. One professor bred a new variety of corn—CAU108, now the most widely grown genotype in China—which, through this company, is 100% owned by our university. It occupies 15% of the area planted to corn. In a sense, the university has become a seed company like Pioneer.

Another professor has bred a new type of chicken—#3 Hen—which consumes much less feed than other varieties while maintaining productivity. Approximately 13 million of these chickens are consumed each year. The Chinese Agricultural University's company assets increased seven-fold from 2000 to 2005.

Part of the company profits are returned to the host institution. About RMB63 million were returned to the Agricultural University last year, and it increases yearly. As president, I use these so-called "free" funds (because they did not come from the government) to subsidize professors' expenses, to finance research and/or teaching or otherwise fulfilling institutional needs.

About 4,500 companies belong to Chinese universities, of which about 50% are high tech.

About 4,500 companies belong to Chinese universities, of which about 50% are high tech. The total annual revenue was US$12 billion in 2004. Accordingly, university companies pay significant taxes to the government, RMB4.8 billion in 2004. Some of these levies are being used to improve China's patenting system and to enforce protection of intellectual property.

Fifty percent of patent applications in China are from foreign countries. Japan is the leader at 9%, then the United States, South Korea, Germany, Netherlands, France, Switzerland, United Kingdom, Italy and Sweden. Of patent applications from within China, Xinghua University is the leader, then Beijing. Some 2,200 applications in 2005 came from the top-ten universities. Universities in Beijing account for about 10% of patent applications.

Professors running these companies made large amounts of money, some of which they gave to their best graduate students.

Challenges

Universities will continue to play a very important role in high-tech business development and innovation, making major contributions to a knowledge based economy in China. As mentioned, Beijing University now has the largest printing-technology company and the biggest for PC producer after Legend/Lenovo computers. And the Chinese Agricultural University has one of the biggest seed companies. The trend will continue; more university companies will be formed and will merge according to marketing patterns.

Management is possibly the biggest challenge. When I left Beijing University as vice president, the annual revenue was US$ 2 billion; I had to oversee six companies, including attending their quarterly board meetings. Professors running these companies made large amounts of money, some of which they gave to their best graduate students. Sometimes this created tension not only among the graduate students, but also among the faculty as more money was to be made in computer science and biotechnology than in mathematics or literature, for example. There is no easy means of managing this problem. Perhaps eventually lessons from the United States will be learned and spin-off companies will be formed. On the other hand, visiting presidents and other representatives from US universities, after expressing surprise, sometimes suggest that the Chinese system should be adopted in the United States.

ZHANGLIANG CHEN—A pioneer in genetic engineering of plants—received his PhD in Roger Beachy's laboratory at Washington University, St. Louis, in 1987. He has served as vice president of Peking University and as director of the China National Laboratory of Protein Engineering and Plant Genetic Engineering, one of China's largest centers for R&D in agricultural biotechnology. Actively involved in biosafety issues, he is a member of the China National Agrobiotechnology Biosafety Committee, which approves field trials and commercialization of genetically engineered crops. He has (co)authored seven books and some 200 research papers.

Dr. Chen has been the president of the China Agricultural University since 2003. He also serves as chair of the Plant Biotech Committee of UNESCO, as a consultant for the International Society for Plant Molecular Biology, and as a member of the Sino-Euro Administration Committee for Biotechnology Cooperation. He was recently elected vice chairman of the Council of Scientific Advisers of the International Center for Genetic Engineering and Biotechnology in Italy.

Function and Role of University-Based Parks In Economic Development

Q&A

Moderator: Steven Pueppke
Michigan State University
East Lansing, MI

Clifton Baile (University of Georgia): Dr. Chen—very interesting story. One thing I didn't understand was the equation that's used in distributing the profit to the university and to the founding professor.

Zhangliang Chen (China Agricultural University): This was a difficult decision because technology differs from department to department; for example, information technology and biotechnology are very different. Actually the policy came from the University of North Carolina and Duke. We decided that 5% goes to the inventing professor, 20% to the department or college and the rest to the university. Later, professors complained that they deserved more as did departments/colleges. So, we changed it, with 40% to the university and 60% shared by the research group and the department/college who decide how it should be distributed. Some departments decided that the money they take will be distributed equally among the professors who have no marketable technology, to provide balance. Different departments have different policies. Other universities may have different policies.

Cholani Weebadde (Michigan State University): When the departments decide to give the funds equally to the professors doesn't the inventor complain again because he gets an equal share?

Chen: No. The inventor gets more money, 5% or 10% for himself. The department chair distributes the rest to the people who have nothing to do with that technology otherwise it causes lots of problems.

Bob Seem (Cornell University): In support of the companies that are involved in your various institutions and organizations, do you treat the biotech companies any differently? Do you provide them any special services? What sort of services might those be, or kinds of advice and assistance that might be provided when the path to market is more difficult?

Allen Dines (University of Wisconsin): In Madison, the University Research Park is one of the few places that actually builds out wet-lab space ready to go for early-stage companies. In that sense, we do provide special assistance for biotech companies. Typically, the track to profitability, the track to products on the market, is a lot faster in IT for example, so we tend to see most of the biotech companies locating at places like the Research Park. At our campus, we have a strong life-science component so we mostly see biotech companies coming from the campus. In fact, some of the IT folks in town get frustrated because they think that there is more attention to, and favors for, the biotechs. However, my sense is that, other than the availability of that wet-lab space, no special programs favor the biotech world and our investors in the Madison area are more interested in the life-science and healthcare side than they are in IT.

Ashley O'Sullivan (Ag-West Bio, Inc.): In Canada, the companies that we deal with particularly through our investment fund—one of the big issues is money and lack of money. These companies live on a day-to-day basis. The CEO of the company usually spends a lot of time trying to figure out how they are going to survive past 3 months from now, because that's all the money they have in the bank. So money is a big issue and we help them through the early stage through the high-risk investment and that "valley of death" space and then we help them to source other capital to begin to move towards the marketplace. The other area in Canada that is a major issue in the life sciences is regulations. Our regulatory system simply does not work and most of our small companies look to the United States first as their market because your regulatory system is easier to get through and the market is larger. We are in the process of providing enhanced regulatory support, to the point of working with the Canadian regulators to try to introduce the new "smart" regulation concept that we have in Canada. And the third major issue for our small biotech or life-science companies is management. We find that a lot of the companies we invest in are technically sound, they are scientifically sound, but they don't understand the marketplace. They don't understand competition. And they don't really understand how to manage a company and work on the quickest path to revenue generation, targeting their most appropriate market opportunities. So, we help them to identify appropriate management to help them be successful.

We find that a lot of the companies we invest in are technically sound, they are scientifically sound, but they don't understand the marketplace.

Wim Jongen (Wageningen Business Generator): We don't make any distinctions in terms of type of companies. It's noteworthy that a number of the companies that have human application come from veterinary science; it seems that veterinary biotech is a nice platform for human applications. We invest in pre-seed, we invest money, also on a case-by-case approach we might co-invest at an early stage to maintain a shareholder position because we want to be active shareholders. In addition we encourage the use the name of the organization, Wageningen-UR, as a way to facilitate things in the market. But, at the end of the day, the market should do its work.

Investment in plant biotechnology in China is very limited.

Chen: It seems to me there should no difference in terms of investment in biotechnology or IT or other areas; a capitalist will invest where money can be made. However there are difficulties with plant biotechnology. Investment in plant biotechnology in China is very limited. It is supported only by the government mainly because of regulatory aspects. As I mentioned before, the commercialization of GM rice remains pending, therefore it is hard for capitalists to justify investing in biotechnology and agriculture. In contrast, investment in pharmaceutical biotechnology is a hot area.

Ken Swertzel (North Carolina State University): A couple of things I'd like to comment on and then I'd like to ask the panel to comment on conflict of interest and conflict of commitment. I'm not so sure that the model in China is so different from the model we have here in the United States. I see us coming together. We certainly have faculty that start companies. We certainly have universities taking equity shares. So universities are owning pieces of companies. We see university faculty staying within the university while they run those companies, and I see those companies investing back into the university in a variety of ways. So, I'm not so sure we are so far apart. Its just more semantics. It seems to me like the bottom line is how you manage the conflict of interest, the conflict of commitment, how you manage dissemination of the information relative to the news media, your state supporters and, of course, the rest of the university community. I'll be interested in your comments.

Dines: We have a special relationship because WARF[1] is an independent entity. WARF is the entity that holds all of the equity in the start-up companies. The university has no equity, so that gives us a kind of a nice, clean starting point with respect to conflict of interest issues. For the most part, the conflict of interest we focus on is the individual conflict. The issue of institutional conflict is something that many universities have not yet waded into. There is a sense of recognition that there are potential pitfalls and problems in that area, but I think there is also the sense that they don't want to kick the sleeping

[1]Wisconsin Alumni Research Foundation.

dog. Because WARF is separate, they can make arm's-length decisions about whom they invest in and when they invest they really just simply take equity in *lieu* of cash for the license agreement. My sense is, there is a substantial difference in what Dr. Chen is talking about in China. As I mentioned, we do not actually form companies—not within the university, not even WARF. WARF takes an interest, but they always let the private sector, the founder, the inventor, pretty much take the lead. That's what I have come to characterize as a *laissez-faire* approach to start-up development. In our institution it seems to be working fairly well that way. Our sense is, we don't want our faculty to be too involved in the management of companies. We prefer to have them stay at the university and continue to do research. That's what they are good at. Typically, they are not all that good at building companies. So we would rather get the faculty person associated with a savvy investor and a savvy entrepreneur who knows how to put the company together.

O'Sullivan: From the Canadian perspective and from our own organizational perspective, we are arm's length from the University of Saskatchewan. When we invest in spin-off companies from the university we are normally dealing with the industry liaison office, which is the arm within the university that licenses all the technologies and establishes the spin-off companies. From our perspective, in terms of our due diligence, we really would like to see the university professor continue with the company. The professor is the key man in the development of the technology and we need that sort of expertise in the company—working with the company—to make sure that it's going to be successful. We may have to get the management expertise from somewhere else, but we really need the technical and scientific expertise. And then we expect that the university, through the industry-liaison office working with the individual professors, will manage any potential conflict of interest.

Jongen: In the Netherlands and in most European universities, we have a different approach, in part in that we are active in pre-seed activities working towards proof-of-concept and also early-stage investment. One of the reasons is that we don't use governmental money to do that; we do it from special funds. My boss is not necessarily happy that the Wageningen Business Generator is the 100% shareholder. I'll give you one example. Last year we had a vaccine-developing company in which there was disagreement between shareholders and I bought the shares from a shareholder so he could leave the company. Suddenly I had more than 50% of the shares so I had to consolidate, and this consolidation within the organization meant there was a multimillion-dollar loss. My boss didn't like that so we are discussing the positioning of my organization. One of the things is that if you are near the university, the balance between representing public good and making money is better guaranteed than when you are more at arm's length and making money is of higher priority. This is a discussion we are currently having in my organization. Professors can take equity in the company and it is their personal responsibility how they deal with that.

Chen: Conflict of interest is a public issue. It's a public university, so on one side you have government money and on the other side you run a company. I visited North

There is conflict of interest for the faculty because you are teaching graduate students while functioning as a CEO.

Carolina State University because it was a pioneer in running enterprises. I also travelled quite often to Stanford and to the University of Maryland and to Japanese universities. In public universities, the possibilities of owning the shares or running a company are limited. But this is what we are doing in China. The people in society are unhappy that the university receives money from the government while faculty members take money from their companies. This creates some problem. There is also conflict of interest for the faculty because you are teaching graduate students while functioning as a CEO. It's a difficult question. It's an experiment, and we'll see what happens in due course.

Allan Eaglesham (National Agricultural Biotechnology Council): In the various entities represented by the speakers, to what extent is optimization of public perception of GM given emphasis?

Dines: In the early 1980s, Madison was the home of the two biggest agricultural biotech company developments. Cetus Madison located there, and after a deal with WR Grace they became Agracetus and about the same time Agrigenetics got started there. You might have noticed in my talk I didn't say much about the agricultural biotech component in Madison. We do have a very strong agriculture school—agriculture and life science, animal science—but because of where the seed money has gone, it's hard to find a true agricultural start-up or early-stage company in Madison. That's changing a little bit. We've got an angel investment group now that's focused expressly on food and agriculture.

To answer your question we have people on the campus that certainly address the policy issues associated with GM-based products. That hasn't been much of an issue in Madison for the companies. I had an interesting conversation with Ralph Hardy last night at dinner. I was at Agracetus at the time they did the first field test of the genetically modified plant and I managed that test from the regulatory and business sides, Similarly, Biotechnica, did the first test of the genetically modified microbe, on the other side of Madison. Both of those field-test locations, for what it may be worth as a little factoid for cocktail party conversation, are now business parks. I'd like to say research parks, but I don't think it's quite true. But they are certainly business parks. A big UPS distribution facility has gone up on one of those sites. So, for what that may mean, I guess the whole idea of genetically modified field-testing going on in Madison, which actually has a tradition of being a very activist and liberal community, was managed very well. We dealt with the regulatory people. We dealt with the public-perception issues and basically it came out very positively. Now, pretty much everybody has forgotten about it, but the fact is there are two fairly historic sites right there, within a few miles of the UW-Madison campus.

We need a regulatory system to protect the public and the environment but also to be an enabler of innovation.

O'Sullivan: In Saskatchewan and in Canada I think we are over the worst in terms of public perception of GM. The rough period that we went through was the late '90s and early 2000. My sense is that the new technologies are fairly well accepted. We have a long track record. As you heard, 90% of our canola is GM. Nobody has grown a third hand or a second head. There is a strong belief that our regulatory system in Canada is protecting the public. It's probably leaning too far on the one side. We need a regulatory system to protect the public and the environment but also to be an enabler of innovation; that's a key piece. We are working with the regulators on that. So, we are really in a reactive mode now. If we see something that clearly is erroneous in the media or in the literature, we react to that as opposed to being proactive on it. Within Canada, there is a $1.2 billion initiative under the auspices of Genome Canada and a number of genome centers have been established—six of them now across the country—and within that is an initiative that deals with ethics, law and society. Those folks are looking at societal issues, legal issues and acceptance issues around GM technology. So, a fair bit of work is going on in the academic community at least, to understand the issue and to make sure we don't repeat some of the problems that we've had with biotech in Canada. The major thing for us at the moment is still the markets and the acceptance of our products in markets, and Europe is still the major issue in terms of GM canola. But I think the tide is turning, even in Europe.

I see a shift in the public perception also in the European context towards the good side.

Jongen: The European perspective on GM was discussed by Peter Welters. The situation in the Netherlands is not much different from the German perspective. When we act in these matters we try to be transparent. Just tell what you are doing. This is one thing. And secondly, as mentioned already, sometimes you rename things to prevent spoilage of discussions. You use different names to explain what you are doing. We follow a similar approach in large programs, as described for the genomics program in Canada. We have a separate program on societal impact discussions; at the initiation of large programs that start, we look the societal context and what problems can be envisioned. Lastly, I am less pessimistic for the mid/long term—I see a shift in the public perception also in the European context towards the good side.

The Phillip Morris Company stated its refusal to import leaves from GM plants in China. Therefore, we stopped that work.

Chen: Public perception for GM in China, mentioned before, is quite confusing. After I returned from Roger Beechy's lab, when I finished my PhD, my own lab carried out the first field trial in China with transgenic tobacco and transgenic tomato, against cucumber mosaic virus and tobacco mosaic virus, both of which severely affect tobacco production. When the experimental area reached a couple thousand hectares, a problem arose. The Phillip Morris Company stated its refusal to import leaves from GM plants in China. Therefore, we stopped that work. And then for tomato, one difficulty is that farmers keep seeds. So, in 2000, we formed a company by ourselves in Beijing University using GM technology and invested a couple of million RMB. But we got nothing out of it because of lack of market demand. Today it is very difficult to invest in the GM area. Monsanto in China produces about 20% of transgenic cotton seeds. We don't have much money invested in GM—it's very confusing at the moment.

The USDA Small Business Innovation Research Program: Vision, Challenge, and Opportunities

William R. Goldner
USDA
Washington, DC

All executive-branch departments with extramural research budgets exceeding $100 million are directed by legislation to provide a 2.5% set-aside to fund SBIR programs.

The Small Business Innovation Research (SBIR) Program is a national competitive funding program, authorized by the United States Congress in 1982 to stimulate and facilitate research and development by US-owned and operated for-profit small businesses. All executive-branch departments with extramural research budgets exceeding $100 million are directed by legislation to provide a 2.5% set-aside to fund SBIR programs. Small businesses are defined as having 500 employees or less.

The United States Department of Agriculture (USDA) Cooperative State Research, Education, and Extension Service (CSREES) manages the SBIR Program. The USDA-SBIR Program awards only grants. It is a three-phase program. Phase I is a feasibility (proof-of-concept) study, and for FY2007 the grant may be for eight months for up to $80,000. Successful Phase I award winners are eligible to apply for Phase II funding. Phase II proposals are for a full R&D project leading to the development of a working product, process, or service that will be ready for final commercial application in the private sector. For FY2007 Phase II awards are for up to 24 months and up to $350,000. Phase III is the actual commercialization phase and no federal funding is used. Historically, companies winning SBIR grants have been successful in leveraging the SBIR seed money and the technical credibility conferred by a confidential and rigorous peer-review process to attract additional investment dollars from private sector entities. Almost half of the companies receiving USDA-SBIR Phase II awards have gone on to have some level of commercial sales based on their project.

The USDA-SBIR Program strongly encourages the participation of university and government scientists in SBIR projects. These scientists may serve as consultants or subcontractors with funding not exceeding a third of Phase I awards or a half of Phase II awards. A public-sector scientist may serve as the principal investigator on an SBIR grant by reducing employment at her/his home institution to 49% for the duration of the grant and if the SBIR research is performed someplace other than her/his lab. It is usually not acceptable for a university or government scientist to serve as a consultant and have all the research proposed for the grant done in her/his lab.

The funding level for the USDA-SBIR Program FY20006 was $19.17 million (Table 1). In 2006, 650 Phase I proposals were received and approximately 16% (101) were recommended for funding (Table 1). During the same year thirty-three of sixty-one Phase II proposals were funded (54%, Table 1).

Table 1. USDA-SBIR Program funding history.

Year	Budget ($million)	Phase I	Phase II
1999	13.3	84[1]/425[2]	32[1]/56[2]
2000	15.6	89/480	36/59
2001	16.3	90/480	37/63
2002	15.7	86/449	39/68
2003	17.7	88/656	38/67
2004	18.2	99/582	38/65
2005	19.2	93/557	40/79
2006	19.2	101/650	33/6`

[1]Proposals funded. [2]Proposals submitted.

Investigator-initiated concepts make up the bulk of the proposals received by the USDA-SBIR Program. The Program has twelve broad topic areas that are outlined in the request for applications (RFA) form (accessible at http://www.csrees.usda.gov/fo/sbir). Of these topic areas, nine routinely field biotechnology proposals (Table 2). This presentation will focus on opportunities and challenges facing researchers submitting biotechnology proposals to two USDA-SBIR topic areas, Plant Production and Protection – Biology and Industrial Applications.

Table 2. Biotechnology-relevant USDA-SBIR Topic Areas

Forest & Related Resources	Aquaculture
Plant Production & Protection–Biology	Industrial Applications
Animal Production & Protection	Animal Manure Management
Water & Soil Resources	Plant Production & Protection–Engineering
Food Science & Nutrition	

Plant Production and Protection–Biology

SBIR Topic Area 8.2, Plant Production and Protection–Biology (P^3B), has three main subtopics:

- Improved Crop Quality and Yield Utilizing Innovative Applications of Plant Breeding, Molecular Biology, Genomics, and Cell and Tissue Biology;
- Development of New Crops as Sources of Food, Fiber, or Industrial Products; and
- Crop Protection from Insects, Disease, and Abiotic Stress.

The USDA-SBIR web site (http://www.csrees.usda.gov/fo/sbir) provides access to abstracts of funded research and success stories that are illustrative of the scope of projects receiving funding in this topic area. From FY2005–2007 "specialty crops" have been a special focus of the P^3B topic area solicitation. Examples of specialty crops are fruits, vegetables, nuts, ornamental nursery or greenhouse crops, and forest trees (*e.g.* American chestnut). Typically, specialty crops have a much lower per-crop market value than the major row crops (*e.g.* corn, soybean). However, taken together they make up fully half of the US annual agricultural output, ~$50 billion (Jerardo, 2005). The P^3B topic area encourages submission of FY2007 proposals in four specialty-crop focus areas:

- improved plant-disease diagnostics;
- improved disease resistance in specialty crops;
- biological approaches to improve floriculture and ornamental nursery production; and
- rapid diagnostic methods for weedy and invasive species.

Although there is great opportunity for small businesses to use the tools and methods of biotechnology to create valuable new specialty-crop genotypes, there are significant challenges, as well. One aspect of the pre-commercial development of any new biotechnology-derived crop is navigating the regulatory process, which may involve interacting with as many as three federal agencies [USDA-Animal and Plant Health Inspection Service (APHIS), Environmental Protection Agency (EPA), and Food and Drug Administration (FDA)]. The time involved and the financial expense of developing a complete dossier for seeking regulatory approval (deregulation) can be daunting. To date, only a small number of transgenic biotechnology-derived specialty crops have been deregulated and allowed to proceed to market (Goldner *et al.*, 2005). Even more troubling is the trend in research to develop specialty crops. Field-trial requests to APHIS for transgenic vegetables peaked in the mid-late 1990s with as many as 120 requests, but by late 2004, it had fallen to approximately twenty (Figure 1). US taxpayers have invested heavily in agricultural biotechnology through the USDA Agricultural Research Service (ARS) and through funding provided to land-grant universities, other public and private universities, and small agricultural biotechnology companies through USDA CSREES. Where is the return on that investment (McHughen, 2005)?

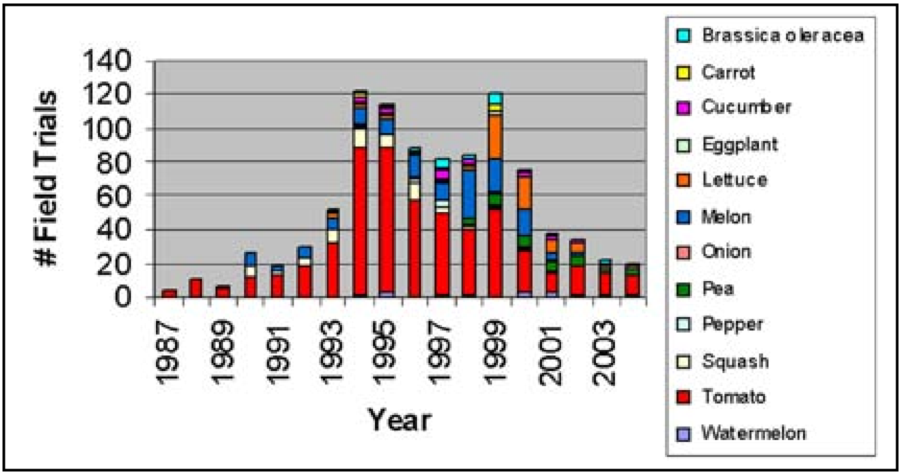

Figure 1. US transgenic fruit and vegetable field trials 1987 to October 2004 (Redenbaugh, 2005)

Biotechnology grants funded by the SBIR Program from FY1998 through FY2006 are shown in Figure 2. One to five Phase I grants in plant biology (P[3]B) have been funded during that period (Figure 2). However, Phase II awards in plant biotechnology receiving peaked in FY2000 (three), with single awards funded in FY2001 and FY2003 (Figure 2). Since 2003, no Phase II award has been granted to a transgenic-technology project in plant

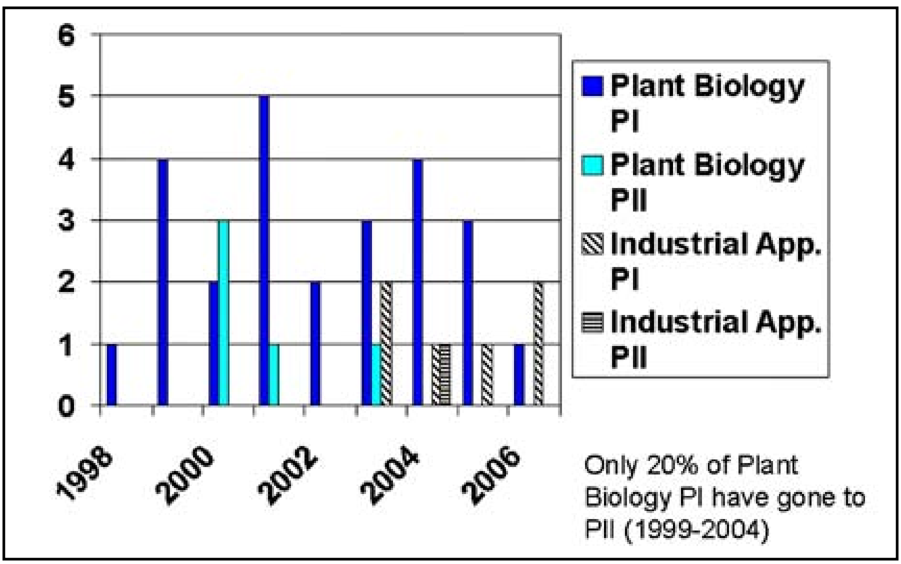

Figure 2. USDA-SBIR biotechnology grants.

biology, despite twelve projects being eligible to apply for Phase II in the FY2004–2006 period (Figure 2). Only 20% of eligible P^3B Phase I projects went to Phase II in the period FY1999–2004 (Figure 2, Phase I projects awarded in FY2005–2006 are still eligible to apply for Phase II in FY2007). Part of the explanation for the low percentage of Phase I projects competing successfully for Phase II may be the increased emphasis on commercial potential that the SBIR Leadership Team developed beginning in FY2003. If it could not be demonstrated how the results of a project would provide a marketable product, overcoming technical and regulatory challenges, there would be reduced incentive for the reviewing community to recommend investment. The question is, "How can we improve the chances for a broad range of biotechnology-derived specialty crops to reach the market place, where market forces will determine their acceptability to the public?"

The Specialty Crops Regulatory Initiative

Motivated by concerns and circumstances outlined above, a team of public- and private-sector scientists and administrators have been working on a program since 2003, The Specialty Crops Regulatory Initiative (SCRI). The over-arching rationale behind SCRI is to facilitate realization of potential to make available a broader range of biotech options, in a greater diversity of crops, to help meet needs of agriculture, consumers, and the environment. Toward this end, the approach being considered is to develop an organization to assist public-sector and smaller-scale private-sector developers of specialty crops through the existing regulatory approval process. Similar programs have been developed to facilitate small-market orphan drugs (FDA) and small-acreage pesticides (USDA, IR-4). Specialty traits of major crops (*e.g.* industrial lubricants, value-added proteins) share similar developmental challenges with specialty crops (*e.g.* smaller market size). At this time, including specialty traits of major crops under the specialty-crops umbrella has neither been ruled in or out.

The over-arching rationale behind SCRI is to facilitate realization of potential to make available a broader range of biotech options, in a greater diversity of crops, to help meet needs of agriculture, consumers, and the environment.

The long-term challenge for SCRI will be to make available a broader range of biotech crop options that create public benefit and meet economic and environmental needs (Goldner *et al.*, 2005). The need for the SCRI is underscored by the diversity of the SCRI steering committee including members from the public sector—USDA-CSREES, ARS, and APHIS, and land-grant universities (1862s and 1890s), as well as technology developers, commodity groups and growers from the private sector. The SCRI steering committee organized and implemented two national workshops to develop the concept and obtain stakeholder input, and have informed numerous scientific and industry groups about the SCRI model. A significant milestone in the realization of SCRI was recently achieved with the selection and hiring of a consultant, through a contract with the University of California-Riverside. The consultant will serve as project manager to obtain additional stakeholder input and support to develop an action plan for realizing SCRI's potential public benefit. While the SCRI is potentially an important entity for providing guidance and assistance in developing critical data sets for specialty crop developers preparing applications for the deregulation of biotechnology-derived specialty crops under the current regulatory system, the implementation of SCRI remains several years in the future.

Alternative Approaches to Developing Specialty Biotech Crops

Despite the decline in SBIR-funded plant biotechnology projects reaching Phase II in the past 3–4 years, there have been some SBIR projects with technical approaches that partially mitigate risk through the implementation of confinement technologies. Two examples are CEA Systems, Ithaca, NY, and Kuehnle Agrosystems Co., Honolulu, HI.

CEA Systems's technology platform was developed at Cornell University. Essentially, the target production of high-value proteins from transgenic plants in controlled environment hydroponic systems (*i.e.* greenhouse, growth chamber). CEA is using SBIR P^3B funding to understand the effects of environment on protein expression in their target crops. The value of the proteins being manufactured is great enough to create a commercially viable opportunity on a greenhouse scale (small acreage) using controlled environment technology to prevent inadvertent environmental release.

Kuehnle Agrosystems (KA) has developed a system of "green biofactories." Their proprietary genetic transformation technology—magnetophoresis—was developed through funding from SBIR P^3B Phase I and Phase II grants. Magnetophoresis allows specific plant tissues or organelles to be transformed resulting in new or optimized metabolic function. KA received an SBIR Industrial Applications Phase I grant to begin developing the use of magnetophoresis to create green biofactories using transgenic unicellular algae that are grown and contained in controlled environment systems. These algae will be capable of producing high-value proteins and other compounds that will justify their relatively small scale of production. The reduced environmental risk conferred by the KA and CEA controlled-environment approach may facilitate the deregulation of their respective biotechnology-derived genotypes to be used exclusively in these systems.

Industrial Applications

The USDA-SBIR 8.8 Industrial Applications Topic Area provides R&D funding opportunities to companies that are developing enhanced production technology, improved quality control, and new biobased products from agricultural materials and residues. For FY2007, the Industrial Applications program established some specific focus areas: biofuels (*e.g.* ethanol, fuel gas, hydrogen); biobased products improving the economics of the biofuel production stream; and the development of new energy crops. USDA plays a lead role in the development of biofuel feedstocks and biomass-conversion technology. Consequently, the SBIR Industrial Applications program is fertile ground for biotechnology

The USDA Rural Development Agency provides a number of programs supporting bioenergy company development and sustainability.

concepts targeting these areas. Figure 2 shows that Industrial Applications biotechnology projects funded by SBIR are on the increase.

The current interest in renewable energy research and development by SBIR was emphasized at a conference held July 6–7, 2006, at Oak Ridge National Labs (ORNL), Oak Ridge, TN. The Department of Energy (DOE)/USDA-SBIR Energy Summit showcased alternative and renewable energy research-funding and technology-transfer opportunities from ORNL and USDA. Approximately 120 scientists and administrators (seventy from small businesses) attended the 2-day conference. Both ORNL (DOE) and the USDA-ARS have extensive research programs on bioenergy, many of which have strong biotechnology components. Additionally, the USDA Rural Development Agency provides a number of programs supporting bioenergy company development and sustainability. CSREES also funds university bioenergy research programs through the National Research Initiative Competitive Grant Program (www.csrees.usda.gov) and through other funding mechanisms. These bioenergy programs may afford new opportunities for small biotech companies to partner with these public-sector research institutions to bring new technologies into application in the private sector.

Additional USDA-SBIR Program Information

The USDA-SBIR Program releases one annual solicitation (usually June 1) with a closing date usually 90 days after the release (usually September 1). Phase I proposals are reviewed by outside reviewers and funding recommendations are provided by a technical review panel. Proposals are submitted electronically. Each applicant receives a verbatim copy of the review and a summary of the panel discussion.

The twelve SBIR Topic Areas are: Forests and Related Resources; Plant Production and Protection–Biology; Animal Production and Protection; Soil and Water Resources; Food Science and Nutrition: Rural and Community Development; Aquaculture; Industrial Applications; Marketing and Trade; Animal Manure Management; and Small and Mid-Size Farms. The website (www.csrees.usda.gov/fo/sbir) may be used to access program information, the RFA, technical project abstracts, links to the Small Business Administration and other SBIR programs, and USDA-SBIR Success Stories.

Closing Thoughts

- USDA-SBIR projects are effective technology-transfer mechanisms for moving publicly developed technology into private-sector applications that benefit various aspects of American agriculture and rural America.

- Royalties and licensing revenues from many SBIR projects accrue to our university partners and other public technology developers (*e.g.* ARS).
- Agricultural biotechnology projects need to be carefully thought out to be competitive in Phase II (commercialization).
- Opportunities are growing for agricultural biotech applications targeting energy-related industrial applications.

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WILLIAM GOLDNER has served as a national program leader for the United States Department of Agriculture, Cooperative State Research, Education, and Extension Service, Small Business Innovation Research (SBIR) Program since 1999. He is responsible for the *Plant Production and Protection (Biology and Engineering)* and *Industrial Applications SBIR* programs.

Dr. Goldner held positions as: associate biochemist at the Hawaiian Sugar Planters' Association (now Hawaii Agricultural Research Center); research scientist/project manager for Union Camp Corporation (now part of International Paper Company); and technical strategy manager for applied genetics in the Biotechnology Development Group for the Global Agricultural Products Division of American Cyanamid Company (now BASF). While at Union Camp and American Cyanamid, he served for six years as an associate professor in the graduate program in Plant Biology at Rutgers University.

Goldner is a member of a team of government, academic and industry administrators and scientists developing a new Specialty Crop Regulatory Initiative to facilitate the timely, cost-effective, movement of transgenic specialty crops through appropriate regulatory processes. He served as chair (with Ann Marie Thro) for the USDA-sponsored workshop *Public Research and the Regulatory Review of Small-Market (Specialty) Biotechnology-Derived Cops* and a recent related workshop, *The Specialty Crop Regulatory Initiative*. He serves on the Commercialization Subcommittee of the USDA Energy Council and on the USDA Biobased Products and Bioenergy Coordination Council, and chaired the July, 2006, DOE/USDA SBIR Energy Summit at Oak Ridge National Laboratory. Goldner holds a PhD in plant physiology from the Pennsylvania State University.

Technology Transfer in the Agricultural Research Service: Implications of Federal / Private Sector, and Federal / University Partnerships to Commercialization Strategies[1]

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The Office of Technology Transfer is key in facilitating these partnerships and in transferring research outcomes for broad beneficial use.

America's food and agricultural producers operate in a global, diverse, and highly competitive marketplace driven by consumers. American farmers are among the most productive in the world and our food and agricultural system provides the nation with the safest, highest quality, and lowest cost food and fiber anywhere. Much of the credit for this success belongs to our public research system and its success in generating new knowledge and technologies that improve productivity and develop new markets for agricultural products.

The Department of Agriculture helps drive continuous innovation through science and technology by forming research and commercialization partnerships with other research institutions and the private sector. The Office of Technology Transfer in USDA's Agricultural Research Service (ARS) is key in facilitating these partnerships and in transferring research outcomes for broad beneficial use by the public and agricultural industries of the United States and other nations. Many of these research outcomes include patented or otherwise protectable technologies. The partnerships include private-sector corporations as well as universities (*i.e.* other public-sector institutions). The mechanisms ARS uses to

[1]Mention of product names is for identification pursposes only and does not imply endorsement by USDA.

commercialize technologies have evolved over the past 25 years in concert with federal legislation that governs federal and non-federal researchers. Federal, state, and private-sector researchers are all working toward the same goal of adopting research results and creating products and services. However, the missions, geographical scope, and accountability to their respective institutions create some real challenges.

This paper describes the "roots" of technology transfer in the United States, the culture of ARS technology transfer, and some observations on how the intersection of technology-transfer authorities has led to convergence as well as divergence among federal and non-federal agricultural researchers in the public sector. Furthermore, some metrics and successes in technology transfer in ARS—some involving partnerships, others strictly in USDA—are provided as illustrations. Finally, we offer a glimpse of what we believe is the future direction of agricultural research.

The People's Department and the Land-Grant System

The "roots" of technology transfer can be traced to the earliest activities that can be defined broadly as "agricultural research" in the United States. Specifically, in 1819 and 1827 the Secretary of the Treasury directed consular and naval officials to transport useful seeds and plants to the United States; the subsequent western expansion during the nineteenth century resulted in the creation of the Section of Foreign Seed and Plant Introduction in 1897 (Shurtleff and Aoyagi, 2004). Frank Meyer (Figure 1) was an early explorer who made many contributions to those collections. Additionally, in 1839, the Patent Office established an Agricultural Division to conduct research. Congress designated $1,000 for "collecting and distributing seeds, carrying out agricultural investigations, and procuring agricultural statistics" [National Archives and Records Administration (RG 07-18), http://www.nara.gov/].

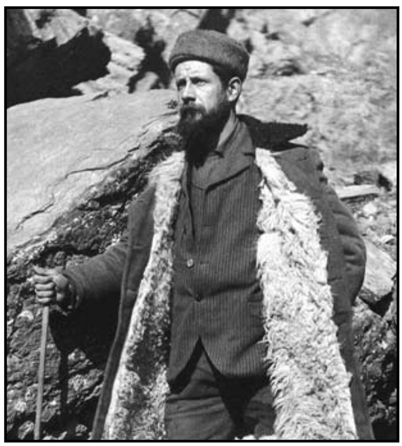

Figure 1. Frank Meyer.

Federally-financed R&D and technology transfer in agricultural research dates from May 15, 1862, when President Lincoln signed a bill that established the Department of Agriculture, or as he coined it, "the People's Department" (Figure 2). The act instructed that the *Commissioner of Agriculture…acquire and preserve…all information concerning agriculture…* Related bills enacted at the same time included The Homestead Act in 1862 and the Morrill Acts of 1862 and 1890 that led to the establishment of major state-operated agricultural research centers. State experiment stations (SAESs) were first established in Connecticut and California in 1875, based on a German model observed by American scientists. The Hatch Act of 1887 later authorized one for each state. Finally, the Equity in Educational Land-Grant Status Act of 1994 (sometimes called the Tribal Colleges Act) brought native American schools into the fold. [For a comprehensive review of the

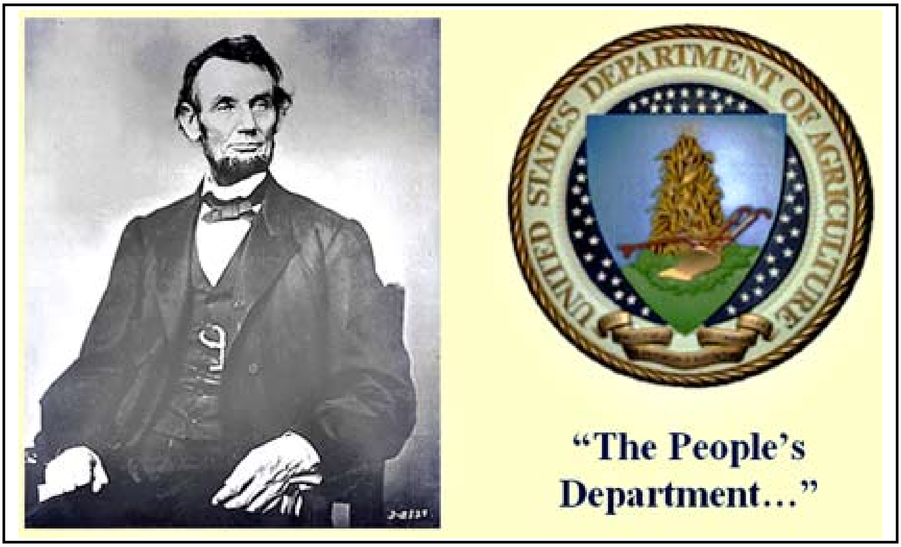

Figure 2. The USDA was established under President Lincoln in 1862.

enabling legislations cited above, see the website for the National Association of State Universities and Land Grant Colleges (NASULGC) at http://www.nasulgc.org.]

Thus, the federal government and the states established an infrastructure for publicly funded agricultural research throughout the United States to conduct research and, ultimately, to transfer results to the public. The collective results of these legislative acts created the 133 land grant colleges and universities in existence today (Figure 3). Even from their very beginnings, USDA has had a special relationship with institutions of higher education. Although USDA scientists have conducted research since the 1860s under various departmental structures, the Agricultural Research Service (ARS) was formally established in 1953. Today, many of our more than 100 ARS facilities are co-located at these institutions and we collaborate on many research projects (Figure 4).

Management of Intellectual Property

Various legislative authorizations over the past 25 years created incentives for the government, universities and industry to work together to commercialize new technologies for the public benefit. However, how intellectual property (IP) is managed depends on the legislative authorizations that, in fact, have critical differences. *Extramural research* funded by federal appropriations are managed according to the Bayh-Dole Act of 1980 that allows institutions performing the research to take title to their inventions and to license rights to practice the inventions without constraints and without notifying the public. In contrast, inventions arising from *intramural research* conducted by federal agencies, such as ARS, are governed by the Stevenson-Wydler Act of 1980 and subsequent legislation, especially the Federal Technology Transfer Act of 1986 and other more recent legislation. (Although these references can be found at many sites, the Defense Technology Informa-

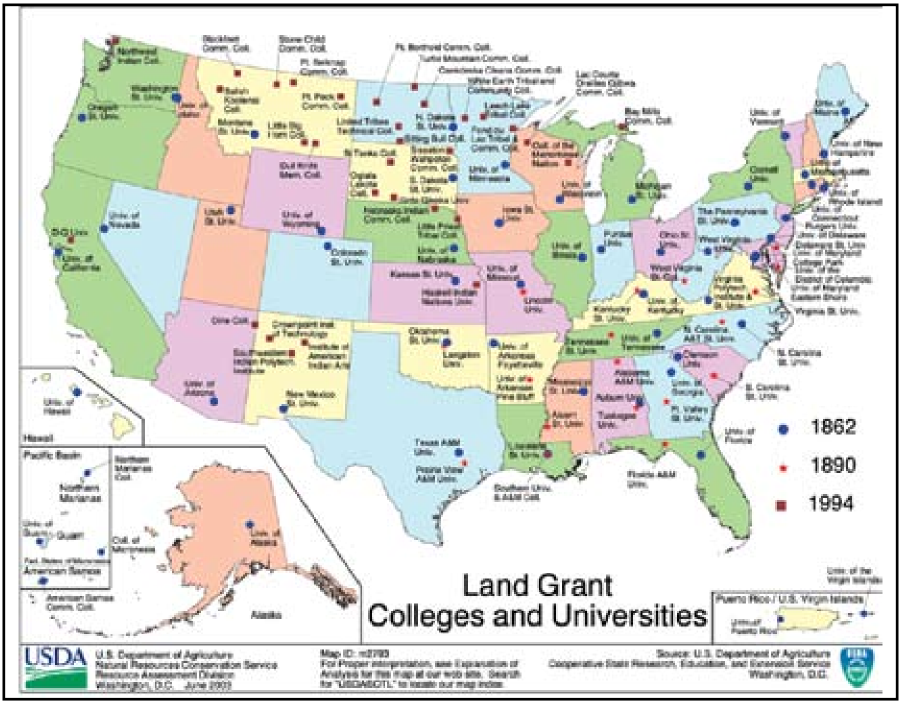

Figure 3. The land-grant network.

We coordinate the technology-transfer activities in ARS, and have the authority to develop and sign a very specific federal instrument for partnerships, specifically Cooperative Research and Development Agreements (CRADAs).

tion Center has a web site that is linked to the Library of Congress Thomas file and has every conceivable legislative action taken in regard to technology transfer: http://www.dtic.mil/techtransit/refroom/laws/).

Collectively, this legislation frames the functions and actions of our Office of Technology Transfer (OTT). We coordinate the technology-transfer activities in ARS, and have the authority to develop and sign a very specific federal instrument for partnerships, specifically Cooperative Research and Development Agreements (CRADAs). We also represent the Secretary of Agriculture on IP management, and have the sole authority for licensing any inventions developed within any of the USDA agencies conducting intramural research, including the US Forest Service, the Food Safety and Inspection Service, and the Animal Plant Health Inspection Service.

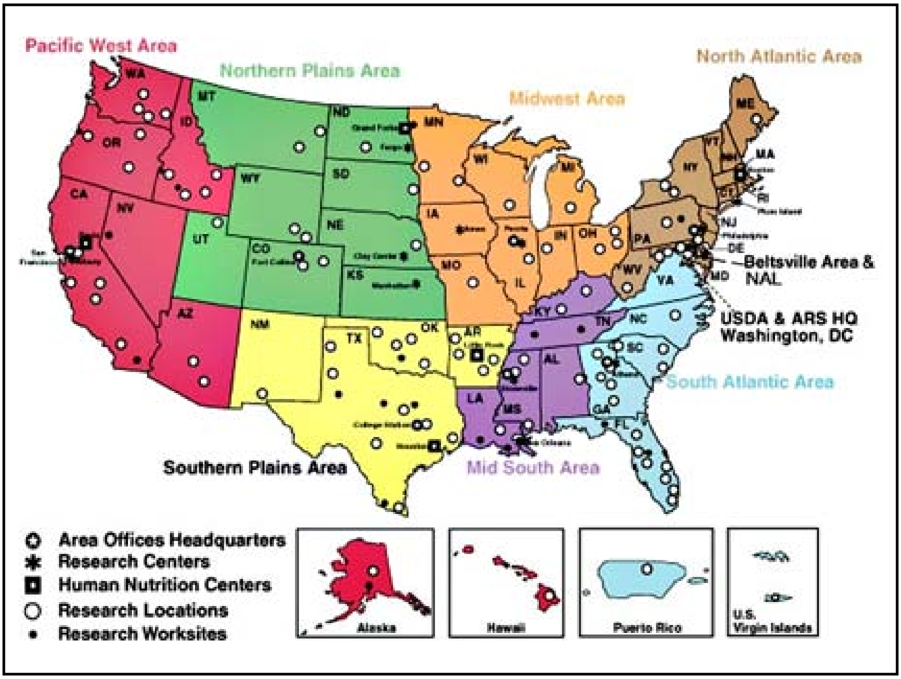

Figure 4. Locations of ARS facilities.

To evaluate the implications of the various legislative acts to our partnerships, we need to frame the context of the ARS policies of today. ARS integrates technology transfer within its research mission, protecting IP when necessary to *facilitate* technology transfer. However, we favor public releases of plant varieties, and avoid patenting "animals" or research tools, and, because we are a public research institution, we promote *further* research by permitting license-free research with any ARS technology. Consequently, the decisions we make relative to licensing federal technologies are governed largely by the goal of facilitating technology transfer for public good in support of US agricultural businesses, not a goal of generating revenue for research.

In licensing IP, two mechanisms have processes highly prescribed by federal statute. First, (also in reference to CRADA involvement) "background inventions" are those that are made by federal researchers under normal intramural research authority with Congressionally-appropriated funds. If a potential licensee requests exclusivity, then we must publish a *Federal Register* notice of our intent to license the specific patent to the applicant company. The purpose is to inform the public so that other qualified individuals or businesses who also want a license to the technology have an opportunity to object to the exclusivity. We then must address all objections. This may result in co-exclusive licenses, or exclusivity by field of use, or in rare circumstances, non-exclusive licenses to all objectors who submit qualified license applications. All of this is prescribed in 37 CFR 404 (Licensing of Government Owned Inventions), and we are diligent in following proper procedures. Federal agencies cannot deny a license to applicants that meet minimum qualifications, except that—all other factors being equal—agencies can grant a preferential license to a small business, but cannot select one small business over any other. Thus, no technology can be preferentially licensed to a local company and denied to others elsewhere. This is a very important distinction between federal and university licensing.

The second mechanism relates to IP developed under a CRADA with a non-federal partner—almost always a private-sector company. This is also a prescribed procedure, but by statute and not by the Code of Federal Regulation (15 U.S.C. 3710a). Inventions made under a CRADA are a distinct advantage for the private-sector company for two reasons. First, the company has the first right to negotiate an exclusive license to at least one predefined field of use without *Federal Register* notice. Therefore, their competition is not only excluded, but remains uninformed. Second, federal agencies can exempt jointly developed data from Freedom of Information Act requests for up to 5 years, but, in practice, ARS rarely grants confidentiality for more than 1 year.

Thus, the laws governing activities of federal intramural research create both synergy and conflict with our partners in public-sector universities. Underlying this is the basic premise that the challenges of global agricultural markets, free trade, and diminishing research funds make these partnerships essential if we are to achieve meaningful research results.

Increasingly, however, federal agencies are often in conflict with university partners as to the goals of protecting IP. From our federal perspective, the goal is adoption of technologies to benefit the public and US industries at minimal transaction costs. We protect IP when it is necessary to achieve technology transfer, but preferred mechanisms are publication of research findings, or public release of technologies. Universities often are forced to make IP decisions on the basis of whether revenues can be generated to support research programs that are strapped by spiraling costs, and diminished federal research dollars. Unless carefully managed, these conflicts can discourage federal/university partnerships.

There is also a degree of conflict in licensing as to regional versus national accountability. Many universities have an appropriate mandate to stimulate economic development preferentially within the region or state. In contrast, federal agencies have to justify processes to the taxpayers of any given state as well as to the taxpayers of the other forty-nine.

ARS is co-located at many educational institutions, and consequently, there is a merging of intellectual capacity with universities. Co-owned inventions frequently result, and unless the federal employee has promptly reported an invention through ARS channels, the university has often moved forward before we have had the opportunity to formally consider options. This can create a problem because our policy *not* to protect certain IP may conflict with the university's policy. Consequently, should we tell the university that, regardless of their intent to issue revenue-bearing licenses, we will make the technology available free of charge, we may find ourselves in the position of spoiling opportunities for our partners.

A final area of potential conflict relates to situations when a USDA researcher uses CRADA funds to hire or contract with a university employee. If joint IP results, we discover that we truly *don't* have consolidated rights to offer exclusively to the CRADA partner (as prescribed by law), because the university has Bayh-Dole rights in the co-owned invention.

Yet, co-owned inventions are common, and we consolidate our rights, usually by licensing ours to the university. This may provide greater flexibility in the sublicensing to private-sector firms because the university may take equity as part of the licensing terms, thereby reducing upfront costs to industry, and no FR notice is required for exclusive licensing.

One disadvantage to co-owned inventions is that universities may prefer to approach licensing from a more regional, rather than a national, perspective. Appropriately, we need to be vigilant to ensure that terms are equitable to commodity groups or industries across state lines.

Reaching consensus on policies beforehand solves joint ownership issues.

Reaching consensus on policies beforehand solves joint ownership issues. When we cannot reach agreement, we may choose to go our own way, rather than to consolidate rights. Alternatively, we may prefer to in-license university rights and then license consolidated rights to industry.

There is a simple proactive solution to the issues of joint inventions made with universities under CRADAs. If ARS needs the university expertise to meet the research mission, we can establish a three-way CRADA to define disposition of IP rights by agreeing that the private-sector partner will have the right to negotiate an exclusive license to any subject invention, regardless of federal or university ownership.

Fruitful Relationships

Despite some of the difficulties described above, these legislative acts have produced beneficial solid relationships. ARS has approximately 200 active CRADAs with the private sector, and separately, over 1,600 cooperative projects with universities where Bayh-Dole rights apply. A total of 320 active licenses are producing 100 products available to the public (Figure 5). Over 120 of these licenses are executed with universities to consolidate rights; twenty-seven of these are producing products from utility patents, plant patents, and Plant Variety Protection Certificates. Thus, there is a demonstrable benefit to the public, to the inventors, and to the publicly funded research institutions conducting the research (Figure 6).

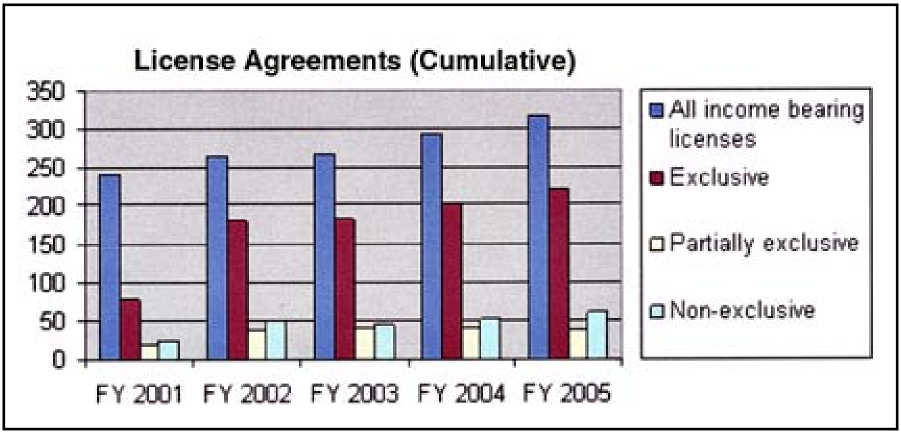

Figure 5. License metrics.

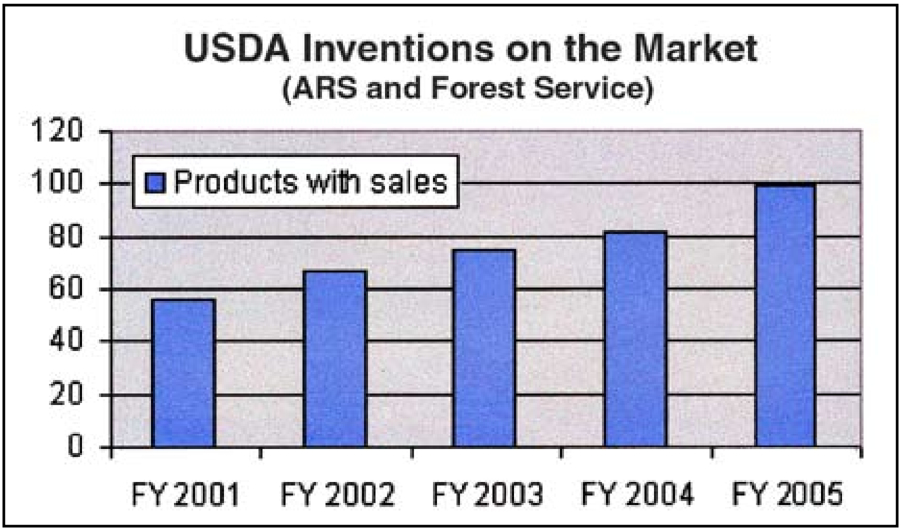

Figure 6. Commercialization of USDA products.

Recognizing that agricultural markets are characterized by thin profit margins requiring exclusivity of rights to protect investments, the majority of our licenses are exclusive. This has not changed over the past 20 years, and additionally, at least 40% of these licenses are with small businesses. Our licensees are increasingly successful at commercializing products with these exclusive rights to our inventions.

New Products

We can illustrate a few current technologies that are on the road to success. For example, ARS developed a technology over the past several years that began reaching expanded markets in 2004. Kids' meals at McDonalds now feature "Apple Dippers," as an alternative to fried potatoes. Apple Dippers are peeled apple slices served with a cup of low-fat caramel dipping sauce. Mantrose-Hauser, a former CRADA partner and current licensee, produces the ARS-developed coating, which is used by apple processors to prevent cut fruits and vegetables from turning brown. A product under the trade name NatureSeal® is being sold commercially to grocery stores, fresh-cut producers and food-service industries. The technology has been extended for sliced avocados, celery, potatoes, carrots, and onions.

Figure 7. Apple Dippers:
Dr. Dominic Wong, one of the ARS inventors of the technology sold under the name "NatureSeal" by licensee.

A grass roots effort for pear growers to add value and create new markets for their products resulted in the development of restructured fruit bars (Figure 8). ARS researchers patented and transferred technology using pureed fruit. Licensed to Gorge Delights, Hood River, Oregon, which built a manufacturing plant and created new jobs in an area with 30% unemployment. Their product line has expanded, and several grocery chains and some US military commissaries now offer these products in several hundred stores. This technology permits year-round processing of seasonal crops from puree through this intermediate "holding" step, and is expected to be used with other crops.

ARS researchers in collaboration with Red River Commodities, Fargo, North Dakota, developed a sunflower butter product—SunButter™—as an alternative to peanut butter. This is especially valuable to persons with peanut allergies. It smells, tastes, feels, and has the appearance of peanut butter. The market for SunButter is expanding to include many uses in baking formerly filled with peanut butter. In January 2004, it was made an entitlement item and added to the official list of available commodities in the National School Lunch Program, and some airlines now include the product in their snack boxes, accounting for a large boost in sales. This was a CRADA development, but there is no patent or license.

Table grape varieties represent an experiment between OTT and the California Table Grape Commission. In this era of global economic markets, a public release of new varieties makes them available to the world, not just to the US industries that provided the tax

Figure 8. Pear Bars: a snack developed by licensee using ARS technology to puree fruits.

base to support the research. Thus, the development of new varieties can inadvertently create a competitive advantage for the rest of the world who may undercut prices because of cheaper labor or unfair trade practices. Therefore, these varieties were protected, and licensed to the California Table Grape Commission (CTGC) for nominal fees to US growers. The CTGC can also sublicense to growers in other countries, thereby gaining some management of growers external to the United States, and further support the research necessary to develop new varieties that favor US growers and consumers.

ARS researchers developed a biodegradable hydraulic fluid made from soybean oil, which is now being used to power the Statue of Liberty's elevator. Until recently, mineral oil formulations derived from petroleum-based stocks were used. The National Park Service contacted ARS scientists requesting development of a biobased fluid that is environmentally friendly, produced from a renewable resource, that is economical and nonpolluting, and meets all industry standards for safety and performance including viscosity, stability, and flame-resistance. ARS researchers already had the know-how to develop this technology. Though other vegetable oils would work, soy was chosen for its low cost, chemical versatility, and availability as a renewable, home-grown resource. Soy is the nation's leading source of food-grade oil, yet only 517 million pounds—3% of the total supply—is used for industrial purposes. The invention, jointly developed with

Figure 9. SunButter™: a non-allergenic alternative to peanut butter.

Pennsylvania State University, was licensed to a start-up company that was immediately acquired by Bunge, a global food and agricultural commodity company, in early 2006; first sales were reported by mid-2006.

70% of the active patent licenses from federal research in labs and universities are in the life sciences with products and processes that feed people, diagnose disease, reduce pain and suffering, and save lives.

The developments in technology licensing reflect how the landscape of agricultural markets has changed during the past 25 years and the growing complexity of our global food and agricultural system. Agriculture, however still must also meet the basic food and fiber needs of people. Interestingly, 70% of the active patent licenses from federal research in labs and universities are in the life sciences with products and processes that feed people, diagnose disease, reduce pain and suffering, and save lives. This doesn't happen, however, by accident, and it is increasingly important to nurture these research partnerships. So where do public research institutes go from here and what opportunities are emerging?

Chemurgy Revisited: Agriculture's Reinvigoration

To see the future, we need to look to the past. In the 1930s, we were using ethanol to power our cars. People like George Washington Carver were working on new uses for agricultural materials (Figure 10). In fact, Henry Ford predicted in 1937, that "… almost all cars will be made of [soy plastic]." In 1940 he installed a plastic trunk lid on one of his personal cars, demonstrating its durability with the blow of an axe (Figure 10). A year later he built an all soy plastic car which was hailed as an"…outstanding industrial achievement" (Henry Ford Museum, http://www.hfmgv.org/exhibits/hf/facts.asp).

Figure 10. George Washington Carver and Henry Ford's soy-based trunk lid.

The movement in which Ford and Carver were involved was called "chemurgy" (Finlay, 2004). Unfortunately, cheap oil sent this nation and its research capacity in another direction. In the context of 2006 issues, the times are indeed changing.

There is an urgent need to become less reliant on imported oil. Biofuels may help achieve this goal. In addition to switch grass, other crops may have potential as feedstocks for biofuels, such as gamma grass, fast-growing willows and poplars, along with biomass residues from traditional agricultural practices.

Additionally, the adoption of biobased products can "back out" petroleum usage through substitution. The federal government—through its massive procurement of goods—can play a role. Title IX of the 2002 Farm Bill put in place federal "preferred procurement" for biobased products (http://www.ers.usda.gov/Features/farmbill/titles/titleIXenergy.htm). This can have a major impact in creating market demand for biobased products and lower unit prices. In cooperation with Iowa State University, a website has been set up to serve as a clearing house for listing biobased products for purchase by federal agencies (http://www.biobased.oce.usda.gov/public/index.cfm).

Given 2006 concerns about rising petroleum prices, our nation will be increasing research emphasis to seek new crops for biotech industrial uses representing new economic opportunities for farmers. Crops that are good for the environment and for rural America and that will reduce our dependence on imported fossil fuels may become priorities. Thus, as a nation we have come full circle. "Chemurgy" has been superseded by "biobased products" and "bioenergy." There is renewed hope that with continuing agricultural research and private/public partnerships created, the products from agricultural materials will be limited only by our imagination: the most prosperous era in American agricultural history is dawning to meet the continuing and expanding needs of the public.

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As assistant administrator in ARS for technology transfer since October 2004, **RICK BRENNER** represents the Secretary of Agriculture on issues pertaining to management of intellectual property arising from USDA research. He has the delegated authority for licensing inventions developed through intramural USDA research, and is a member of the Interagency Working Group for Technology Transfer convened monthly by the Department of Commerce Office of Technology Policy.

From August 2001, Dr. Brenner served as the deputy assistant administrator for the Office of Technology Transfer, USDA-ARS, where he managed much of the daily operations on Cooperative R&D Agreements (CRADAs), patents, and licensing. From 1984, he served as an entomologist and later as a research leader for ARS in Gainesville, Florida. His research led to a number of awards, including Outstanding Senior Scientist, the USDA Award for Superior Service, the ARS the Technology Transfer Award, a Federal Laboratory Consortium Technology Transfer Award, and the *Pollution Prevention Project of the Year* award in 1999 under the Strategic Environmental Research and Development Program, jointly awarded by the Department of Defense, Department of Energy and the EPA.

Brenner has a PhD in medical entomology from Cornell University, and two degrees from the University of Illinois.

From the Bench to a Product: Academics and Entrepreneurship

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I will provide a case study of my experience in trying to translate basic research discoveries into a product via a startup company. As an academic, a university professor—managing a grants program and students—why start a company? One of the things that drove me was my expertise in the area of *Bacillus thuringiensis* (*Bt*) toxins and their applications for insect control. If you stay in a research area long enough, you acquire insights into limitations in current technology and, if you have an entrepreneurial bent, you look for opportunities to apply those insights and solve problems. Also, as you do basic research, whether in a university or private-sector laboratory, you may ask the question, "Where is it going?" You are building blocks of knowledge, but then you begin to look for opportunities to commercialize these technologies. In the 1980s while at Agrigenetics, I was involved in the process of patent writing. This experience proved invaluable when, at the University of Georgia, I began to evaluate research in my laboratory for potential inventions. My university was supportive in paying the costs of patenting, but then another bottleneck in the process emerged. You may have an invention, but the technology is at such an early stage in development, a large company is not likely to license the technology. So you look for ways to bridge the gap between the initial lab results and a product.

Despite the difficulties that plagued agricultural biotechnology in the 1990s, I looked for opportunities in the agbiotech sector. It seemed that with consolidation in the industry dominated by a few large companies, there might be a niche for creating a startup company focused on insect control. On the other hand, despite having experience working in a biotech company, I questioned whether I had the energy and desire to enter the business world. But then things came together, helping me cross that line to form a company with the help of colleagues, albeit without a vision of the amount of time it would take.

The University of Georgia has a commercial alliance program to help professors who desire to be entrepreneurs combine their efforts with people who know how to build businesses.

Seeking New Strategies In Insect Control

In 2003, Dr. Clifton Baile (University of Georgia, UGA) and I founded a company called InsectiGen, seeking new strategies for insect control. The UGA has a commercial alliance program that functions together with the Georgia Research Alliance to help professors who desire to be entrepreneurs combine their efforts with people who know how to build businesses. Located on campus at UGA is a Center for Applied Genetics Technologies, which makes available high-tech instrumentation to startup companies. In addition, the Georgia BioBusiness Center, directed by Dr. Margaret Wagner Dahl, helped provide infrastructure for founding InsectiGen.

InsectiGen went through the traditional startup phases of identifying intellectual property and market opportunities and writing a business plan. The Georgia Research Alliance has a program that provided funding to allow us to hire a professional to write the business plan. We moved to proof of concept and to development over the last year or so, securing capital and building infrastructure to go from a virtual company to a real company.

InsectiGen

I am fortunate to have Cliff as a motivational leader who has experience as a university professor, as a director of R&D at Monsanto, and as founder of seven biotech startups, as well as being director of a fairly large agbiotech company, MetaMorphix. He has provided the knowledge-base to make InsectiGen a reality.

Robert Ligon had retired after 25 years in informational technology entrepreneurship when he took my class at the University of Georgia on biotechnology. He became more interested and involved in the work, and ultimately served as president of InsectiGen. During that time, he helped develop the first business plan.

Having worked in the *Bt*-toxin area for 25 years, I provide scientific leadership. My work developing *Bt* plants has led to a number of patents and their commercialization in a small company. My colleague of many years, Don Dean, and I shared an NIH grant to design new *Bt* toxins for mosquito control; Don had the knowledge base, as well as the desire, to help me in this business endeavor. Dr. Mohd Amir Abdullah, who is paid from an USDA Small Business Innovation Grant awarded to InsectiGen May 1, 2006, has been working in my lab on InsectiGen projects for 2 years.

Having an Impact

We founded InsectiGen in 2003. The question we had to ask, in terms of finding a niche, was "How in the world, with such tremendous success with *Bt* corn, with *Bt* cotton—with major players involved—can a couple of people in a little company actually have an impact and do something useful?"

We think that we can.

We know that there are unmet needs both in controlling insects that are currently only partially knocked down by *Bt* cotton and in developing new targets for *Bt* crops, for example corn rootworm. We think that our technology will augment what's already available.

I know that we can help improve the efficacy of *Bt* biopesticides, which is a commodity-based global market of about $250 million. The numbers are a little hard to come by, but in the United States it's a $76 million to $100 million market that has been stagnant for the last 10 years, partly due to *Bt* crops, because of limited biopesticide persistence, limited insect-control spectrum and development of insect resistance, but mostly because *Bt* biopesticides are relatively expensive at $15 to $20/acre. Therefore, at InsectiGen we are looking for strategies to make *Bt* biopesticides less expensive and more effective.

BtBooster

We came up with a new technology that was discovered from basic research: we call it BtBooster. It's a protein-based agent that enhances the effect of *Bt* toxins. Stacked with *Bt* genes in transgenic plants or combined with *Bt* biopesticides, it improves control of insect pests.

In my laboratory we have been focused on the general question of how *Bt* toxins kill insects and how insects adapt to become resistant to *Bt*. Ingested *Bt* crystals dissolve in the insect gut where they are processed by proteases, converting protoxin to activated toxin. The toxins bind receptors located in the insect mid-gut, analogous to a lock-and-key mechanism. The actual events involved in toxin action are quite complex, involving contact with multiple receptors, formation of a pre-pore structure followed by membrane insertion and cell death.

From our basic research, we discovered that a fragment of a receptor protein made in *E. coli*—BtBooster—enhanced toxicity when mixed with *Bt* protein. This presented the possibility of taking a *Bt* plant that only marginally kills some insects and genetically stacking it with BtBooster peptide to achieve more-effective control of those insects. Our goal is to combine BtBooster with *Bt* proteins in transgenic crop plants and with *Bt* biopesticides.

There are many barriers that prevent a startup company from selling genetically engineered cotton and corn. Therefore, it was necessary that InsectiGen license the BtBooster technology to a large company. In this case, DuPont licensed the use of BtBooster in cotton and other crops. InsectiGen will develop *Bt* biopesticides using BtBooster.

Funding and Sustainability

Founding partners and friends contributed funds to launch InsectiGen. The company's founding was based on a vision rather than a specific technology, or even BtBooster. With a business plan we raised money from friends and "angel investors." The Georgia Research Alliance was instrumental by matching dollar-for-dollar funds that InsectiGen spent on research. InsectiGen received an investment from the Georgia Venture Partner / Georgia Biosciences seed capital fund, monies put forth by Georgia as well as by universities to stimulate development of startup biotech companies. Having a licensing agreement with Dupont-Pioneer greatly enhanced our ability to raise funds.

Recently, InsectiGen was awarded a Phase 1 Small Business Innovative Research (SBIR) grant from the USDA[1]. The Phase 1 grant supports the testing of a BtBooster-*Bt* biopesticide in greenhouse trials. Pending a successful outcome of greenhouse studies, InsectiGen can apply for a Phase 2 grant to support field trials. Phase 3, actual commercialization of a biopesticide, would then be funded by InsectiGen.

You start out as an individual—a university professor—with entrepreneurial spirit, and one of the first things that people ask is, "What is your vision for the company?" People would ask, "Are you a lifestyle company?" "Will it be a small company that will stay within your economic control, for a period of years?" "Or are you going to go the route of raising capital, first through investors and then through venture capitalists?" In the latter case your vision as the professor-entrepreneur has to be balanced by that of the CEO, by your investors, by your directors on your board. You quickly learn that you have less control than you ever expected, which you have to be willing to accept.

Another thing that I've learned is that, in spite of what you may think, professors are not the best managers. Running an academic research group is quite different than managing science in a startup biotech company. In business, even at the scientific level, at some point you may need people who are better managers.

You also must deal with ethical conflicts between the role of the entrepreneur—which can be time-consuming—and the role of the professor with obligations to students, etc.

Ethics and Time Challenges

You also must deal with ethical conflicts between the role of the entrepreneur—which can be time-consuming—and the role of the professor with obligations to students, to postdocs, to research colleagues, and to others in the university milieu. You must learn to balance teaching responsibilities and a university-based research program with time spent on company business. Issues of potential conflict between academic responsibilities and the biotech startup are addressed through a formal policy system based on open-disclosure with university administration and researchers in the academic laboratory. In my case, the associate dean for research in the College of Agriculture and Environmental Sciences is the hands-on manager for conflicts, with whom I have to dialogue in order to circumvent problems.

Time management is one of the major challenges. In my lab we have grants from USDA and NIH, and as well as InsectiGen-sponsored research. Between science-management issues, research duties, teaching, and company obligations, the process of academics as entrepreneurs can be made to work, but it truly is a struggle.

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[1]William Goldner's description of the SBIR Program is on pp. 149–156.

The business of commercializing products is very different from academia, particularly in terms of the number of challenges—and failures—that you have to deal with.

In Summary

I have tried to provide a snapshot of my personal experience and I will conclude by saying that it's both challenging and rewarding. As a professor you're never sure what the final outcome of these endeavors is going to be. One of the things I'm interested in doing is communicating with faculty at other universities to address common issues that come up in business-related endeavors.

And then, finally, a parting thought from Alejandro Zaffaroni, who has started a number of companies including Hybritech: you learn that the business of commercializing products is very different from academia, particularly in terms of the number of challenges—and failures—that you have to deal with.

MICHAEL ADANG received his BS in microbiology from Indiana University in 1974 and his MSc and PhD in bacteriology from Washington State University in 1978 and 1981. He is a professor of entomology, biochemistry and molecular biology at the University of Georgia with ninety journal articles and book chapters and thirteen US patents to his credit.

As a senior research scientist at Agrigenetics Corp. in Madison, Wisconsin, 1982–1988, Dr. Adang developed transgenic plants expressing proteins from *Bacillus thuringiensis* (*Bt*). Among his inventions are methods for expressing *Bt* genes in plants and a codon-usage method to optimize *Bt*-gene expression in plants. These technologies have been used worldwide with significant impact on pest control in agriculture.

Since 1988, his research has focused on receptors that determine *Bt* toxicity to insects. His laboratory was the first to discover a *Bt*-toxin receptor, with basic and applied implications for *Bt*-plant development and usage.

Adang has consulted for the government, Mycogen Corporation and Dow Agrosciences. His global activities in the intellectual-property area include patent preparation and prosecution activities with approximately ten law firms over a 20-year period. In 2003, he co-founded InsectiGen, a start-up company focused on discovery and engineering of proteins for insect control.

Thoughts about the Twenty-First Century Biotechnology Workforce

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Economic and workforce development are unusual topics for the National Agricultural Biotechnology Council. I will discuss aspects of the workforce in general and the biotechnology workforce in specific. First are some thought-provoking views about changing demographics and global competition; second is information on skills needed in the twenty-first century workplace and the mindset of the current generation; and third is one California educational institution's approach to dealing with these changes to provide a well-trained biotechnology workforce to serve business and industry.

Technology, Demographics and Global Competition

The effects of technology upon the current generation are significant. According to Martin Beam (personal communication, 2006), college students today rate their iPODs of more importance than beer. Instruction is available electronically through distance-learning, blogs (or Web logs), and World Wide Web sites. These new sources of learning widen the gap between the generations. Technology-savvy youngsters plunge in readily with electronic devices whereas oldsters, many of whom are unable to turn on a computer, hold the view that formal education is available only outside the home.

Noticeable also are changes in ethnic background of students. In California, there is no longer an ethnic majority. Although only California statistics are included in this article, California can be considered a microcosm of the United States regarding the trends that these statistics imply. In California, the demand for highly educated workers combined with the loss of retiring highly educated workers is equal to more than 3 million, equal to the combined populations of the cities of San Diego, San Jose and San Francisco (Campaign for College Opportunity, 2006).

Below is a summary of a landmark study by researchers at UC Berkeley—*Return on Investment: Educational Choices and Demographic Change in California's Future*—of the state's demographic future and the return on investment for expanding college opportunity.

For every dollar spent increasing the number of students attending college and completing degrees, the state gets three dollars in net return on that investment.

The study finds that for every dollar spent increasing the number of students attending college and completing degrees, the state gets three dollars in net return on that investment. The report also provides critical demographic projections for the State's future population. During the 1990s, California became a minority-majority state as the non-Hispanic White population fell below 50%. By 2000, the population of California was 47% non-Hispanic Whites, 32% Latino, 12% Asian, and 7% African American. The California population is expected to grow to 43 million by the year 2020 and to 55 million by the year 2050, with most of this growth driven by increases in minority populations.

[Here are] a few quick snapshots at some of the trends in the African American, Latino and the Asian Pacific Islander population. For more detailed snapshots for each of these ethnic groups, visit our website at www.collegecampaign.org.

Key Findings

- Among 18–24 year olds, 28% of African Americans lack a high school diploma and only 40% report any college attendance. Although African Americans have college-going rates comparable to non-Hispanic Whites, they have extremely high drop out rates from college as a group and earn Baccalaureate degrees at one of the lowest rates amongst all ethnic groups. Only 45% of 18 year-old African Americans are expected to go to a public college in California, only 19% will reach a public 4-year university and only 9% earn a Baccalaureate Degree there.

- Latinos are the fastest growing population, growing by more than two-thirds from 2000–2020. Growth in the Latino population is striking for all age groups in the state, but this growth is particularly critical among the college-going age group (18–24 year olds). In this age group, Latinos are most likely to have no high school diploma and least likely to have entered college. Less than one third of 18 year-old Latinos are expected to go to a public college in California, only 15% will enter a public 4-year university and only 10% will earn a Baccalaureate Degree there.

- The Asian and Pacific Islander population has grown tremendously in the past few decades. Their levels of college-going and rates of degree completion are the highest amongst all ethnic groups, including non-Hispanic Whites. Nearly 80% of 18-year old Asians are expected to go to a public college and nearly 43% will earn a Baccalaureate Degree there.

Conclusion

The study makes it clear that the return on investment is very positive for the state. For every dollar spent increasing the number of students attending college and completing degrees, the state gets three dollars in net return on that investment. This snapshot provides sobering information to focus attention on encouraging higher rates of high school graduation for Latinos and African Americans, and improving the success of those who do graduate from high school and enroll in college. We must continue to encourage and support college participation and success amongst Whites and Asian/Pacific Islanders and we must increase college participation and success amongst all our young adults. Given what we know about the positive return on investment, the future workforce needs and the growing number of young adults, this information is a call to action." (Brady *et al.*, 2005)

A sobering report from the National Association of Manufacturers points out global competition issues and that the current US workforce is unprepared.

Yet below the seemingly calm surface [of rising productivity in the US] an undercurrent of uncertainty is roiling the emotional waters for American workers. Rapid changes in technology and intense global competition—particularly from Asia—have fomented a gnawing anxiety about the future. If we are to alleviate this anxiety, keep our economy strong and successfully compete in the fiercely competitive international race to the top, we must recommit our nation to innovation and the concerted development of a more highly educated and skilled workforce.

Indeed, the world has changed over the past decade. In 1993, the United States alone accounted for 29 percent of global production. The 10 largest economies accounted for three-quarters of the world economic output and, among these top-ten, the only developing nations, Brazil and India, ranked 9 and 10, respectively. Fast forward ten years to 2003: the United States remained the largest economy, but its share of global output had fallen to 21 percent. The 10 largest economies accounted for just two-thirds of the world economy and, with China and Russia supplanting Canada and Spain, just six of the top 10 countries were traditional industrialized democracies. Today the global economy is more competitive across a broader number of nations. Faster growth in the developing world has spilled over into global trade…

A more integrated global economy, with more import competition and more export opportunities, offers both new challenges and opportunities to the United States and its workforce. To succeed, it is essential that the U.S. maintain its position as the world's leading innovator.

Looking back over the 20th century, American ingenuity has been truly incredible…Going forward, new innovations will continue to be critical, both in maintaining a solid industrial base and increasing our standard of living. In short:

Innovation leads to new products and processes that sustain our industrial base.

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1. Innovation leads to new products and processes that sustain our industrial base.
2. Innovation depends on a solid knowledge base in math, science and engineering.
3. Without this knowledge base, innovation as well as our industrial base will erode.

Our economy's ability to compete in the 21st century will not be influenced by past performance. Success or failure will be determined primarily by our capacity to invent and innovate. Unfortunately, there are troubling signs that the American workforce is not ready to meet innovation's challenge, and our position as leader of the global economy is threatened." (Labor Day Report, 2005, pages 1 and 2)

Skills and Mindset Changes

Skills

Workplace competency and technical skills sets have changed, as outlined in Table 1. For instance, computer literacy was not a required workplace skill in the twentieth century, whereas, in this century, not only do workers need to know how to operate a computer, they need advanced computer literacy to function as a bank teller, auto mechanic, nanotechnology specialist, scientist, delivery truck driver, or quality-control specialist.

Table 1. Differences in workplace skills and competencies: twentieth vs. twenty-first century (Koehler, 2006).

Twentieth century	Twenty-first century
General literacy	Science literacy
Arithmetic literacy	Math literacy, equations
No computer literacy	Advanced computer literacy
Basic shop equipment	Scientific laboratory equipment
Conversational English	Specialized technical English
Follow instructions	Innovation and problem-solving
No writing and analysis	Technical report preparation and interpretation
Individual job responsibility	Capacity to form and innovate in mixed groups
One-time learning of advanced competencies	Life-long learning of different advanced competencies

In biotechnology, including agricultural biotechnology, skills sets include the technical aspects. However, rated more important by employers are the so-called "soft" skills, which are actually sometimes more difficult than technical skills: working in teams, communicating in written and verbal English, presenting data to groups, getting to work on time, putting in a full day of work, and having competency with a computer (Koehler and Koehler-Jones, 2006). These "soft" skills are also named workplace competency skills.

Basic technical skills in biotechnology include:

- Mathematical competency for understanding several procedures: dilutions, solution making, pH calculations, buffers, and other related procedures;
- Understanding what pH is and why it is crucial: for instance, knowing that an excursion from pH 7 to pH 9 could potentially kill the cells with which you are working;
- Understanding molarity and using it for solution making;
- Basic cellular biology;
- Basic molecular biology;
- Basic chemistry;
- Basic microbiology;
- Sterile technique.

Advanced skills, too numerous to list, are expansions of the above, with specialized training provided either on the job by the employer for unique requirements, or by an institution of advanced learning that collaborates with companies to provide needed skills.

Mindset

Attitudes to work alter from one generation to the next. The veteran generation—born between 1920 and 1942—are seen as mentors who understood their obligations to family and country. Baby boomers—born between 1943 and 1965—are now the older worker pioneers. Generation Xers—born between 1966 and 1979—are considered cautious and self-reliant skeptics. For this generation in the United States, international competition is noteworthy: issuance of 14 million college degrees is expected in the United States in 2010 (41% to women), and 16 million will be issued in China.

The Net generation—born between 1980 and 1995—is eager to innovate and change the world. They expect good wages, are nationalistic and have strong cultural values (*e.g.* Latinos are family-oriented), have high-tech skills which could widen the digital divide, they expect to have multiple jobs and careers, want a balanced life, do not consider baby boomers as role models, and they consider gender equality to be a given.

Another factor worthy of consideration is the mindset of the current generation. An informative source on this subject is the Beloit College Mindset List® (http://www.beloit.edu/~pubaff/mindset/), a gathering of ideas to prevent "hardening of the references," according to authors Tom McBride and Ron Nief.

Summer 2005. In the coming weeks, millions of students will be entering college for the first time. On average, these members of the Class of 2009 will be 18 years old, which means they were born in 1987. Starbucks, souped-up car stereos, telephone voicemail systems, and Bill Gates have always been a part of their lives.

Each August, as students start to arrive, Beloit College releases the Beloit College Mindset List, which offers a world view of today's entering college students. It is the creation of Beloit's Keefer Professor of the Humanities Tom McBride and Director of Public Affairs Ron Nief.

McBride, who directs Beloit's First Year Initiatives (FYI) program for entering students, notes that "This year's entering students have grown up in a country where the main business has become business, and where terrorism, from obscure beginnings, has built up slowly but surely to become the threat it is today. Cable channels have become as mainstream as the 'Big 3' used to be, formality in dress has become more quaint than ever, and Aretha Franklin, Kermit the Frog and Jimmy Carter have become old-timers."

The list is distributed to faculty on campus during the New Students Days orientation. According to McBride, "It is an important reminder, as faculty start to show signs of 'hardening of the references,' that we think about the touchstones and benchmarks of a generation that has grown up with CNN, home computers, AIDS awareness, and digital cameras…these students missed out on the pleasures of being tossed in the back of a station wagon with a bunch of friends and told to keep the noise down, walking in the woods without fearing Lyme Disease, or setting out to try all of the 28 ice cream flavors at Howard Johnson's."

According to Nief, "This is not serious in-depth research. It is meant to be thought-provoking and fun, yet accurate. It is as relevant as possible, given the broad social and geographic diversity of our students, who are drawn from every state and 50 countries. It is always open to challenge, which has an additional benefit in that it reminds us of students' varied backgrounds."

BELOIT COLLEGE'S MINDSET LIST®

Most students entering college in the fall of 2005 were born in 1987.

1. Andy Warhol, Liberace, Jackie Gleason, and Lee Marvin have always been dead.
2. They don't remember when "cut and paste" involved scissors.
3. Heart-lung transplants have always been possible.
4. Wayne Gretzky never played for Edmonton.
5. Boston has been working on the "The Big Dig" all their lives.
6. With little need to practice, most of them do not know how to tie a tie.
7. Pay-Per-View television has always been an option.
8. They never had the fun of being thrown into the back of a station wagon with six others.
9. Iran and Iraq have never been at war with each other.
10. They are more familiar with Greg Gumbel than with Bryant Gumbel.
11. Philip Morris has always owned Kraft Foods.
12. Al-Qaida has always existed with Osama bin Laden at its head.
13. They learned to count with Lotus 1-2-3.
14. Car stereos have always rivaled home component systems.
15. Jimmy Swaggart and Jim Bakker have never preached on television.
16. Voice mail has always been available.
17. "Whatever" is not part of a question but an expression of sullen rebuke or indifference.
18. The federal budget has always been more than a trillion dollars.

19. Condoms have always been advertised on television.
20. They may have fallen asleep playing with their Gameboys in the crib.
21. They have always had the right to burn the flag.
22. For daily caffeine emergencies, Starbucks has always been around the corner.
23. Ferdinand Marcos has never been in charge of the Philippines.
24. Money put in their savings account the year they were born earned almost 7% interest.
25. Bill Gates has always been worth at least a billion dollars.
26. Dirty dancing has always been acceptable.
27. Southern fried chicken, prepared with a blend of 11 herbs and spices, has always been available in China.
28. Michael Jackson has always been bad, and greed has always been good.
29. The Starship Enterprise has always looked dated.
30. Pixar has always existed.
31. There has never been a "fairness doctrine" at the FCC.
32. Judicial appointments routinely have been "Borked."
33. Aretha Franklin has always been in the Rock and Roll Hall of Fame.
34. There have always been zebra mussels in the Great Lakes.
35. Police have always been able to search garbage without a search warrant.
36. It has always been possible to walk from England to mainland Europe on dry land.
37. They have grown up in a single superpower world.
38. They missed the oat bran diet craze.
39. American Motors has never existed.
40. Scientists have always been able to see supernovas.
41. *Les Miserables* has always been on stage.
42. Halogen lights have always been available at home, with a warning.
43. "Baby M" may be a classmate, and contracts with surrogate mothers have always been legal.
44. RU486 has always been on the market.
45. There has always been a pyramid in front of the Louvre in Paris.
46. British Airways has always been privately owned.
47. Irradiated food has always been available but controversial.
48. Snowboarding has always been a popular winter pastime.
49. Libraries have always been the best centers for computer technology and access to good software.
50. Biosphere 2 has always been trying to create a revolution in the life sciences.
51. The Hubble Telescope has always been focused on new frontiers.
52. Researchers have always been looking for stem cells.
53. They do not remember "a kinder and gentler nation."
54. They never saw the shuttle *Challenger* fly.
55. The TV networks have always had cable partners.

56. Airports have always had upscale shops and restaurants.
57. Black Americans have always been known as African-Americans.
58. They never saw Pat Sajak or Arsenio Hall host a late night television show.
59. Matt Groening has always had a *Life in Hell.*
60. Salman Rushdie has always been watching over his shoulder.
61. Digital cameras have always existed.
62. Tom Landry never coached the Cowboys.
63. Time Life and Warner Communications have always been joined.
64. CNBC has always been on the air.
65. *The Field of Dreams* has always been drawing people to Iowa.
66. They never saw a Howard Johnson's with 28 ice cream flavors.
67. Reindeer at Christmas have always distinguished between secular and religious decorations.
68. *Entertainment Weekly* has always been on the newsstand.
69. Lyme Disease has always been a ticking concern in the woods.
70. Jimmy Carter has always been an elder statesman.
71. Miss Piggy and Kermit have always dwelt in Disneyland.
72. *America's Funniest Home Videos* has always been on television.
73. Their nervous new parents heard C. Everett Koop proclaim nicotine as addictive as heroin.
74. Lever has always been looking for 2000 parts to clean.
75. They have always been challenged to distinguish between news and entertainment on cable TV." (McBride and Nief, 2005)

One California Educational Institution's Effort to Meet the Biotechnology Workforce Need

One of the most compelling issues about the workforce is its weight in corporate decisions and planning. In a 2002 corporate survey, CEOs were asked to rank factors according to their importance in choosing a business site; availability of skilled labor ranked first, with cost of labor second. The same survey in 2003 saw cost of labor again in second place, while availability of skilled labor came in third, at 89% (Gambale *et al.*, 2003).

Biotechnology and nanotechnology—sets of skills and procedures already used in many businesses—will change how almost everything is manufactured, used, and recycled. Since these technologies are ubiquitous, estimating workforce need is a conundrum. A reasonable guess for the biotechnology industry cluster in California is that this workforce will, by 2010, be in the range of 882,000, including pharmaceuticals, medical and dental labs, measuring and control devices, medical instruments, research and testing, engineering services and management and public relations. This is an increase of nearly 200,000 workers from 2000, *i.e.* about 20,000 per year. (Koehler and Koehler-Jones, 2006)

The executive summary of an eighty-page report, *California's Biotechnology Workforce Training Needs for the 21st Century*, (Koehler and Koehler-Jones, 2006), outlines how to determine workforce needs and how to meet them.

As used in this report, Biotechnology refers to the application of scientific advances in the life sciences to create commercial products and services. The biotechnology industry cluster includes all of the support services and manufacturers of various instruments, reagents and other products that support the research, testing, and manufacturing of biotechnology products. Bioindustry firms can be organized into eight categories based on their end markets: therapeutics, diagnostics, agricultural, bioremediation, energy, materials including chemicals, bioindustry suppliers, and bioinformatics (each sector is defined in the report*).*

This study forecasts the biotechnology industry's workforce skills training requirements anticipated over the next five years to ten years. The forecast is based on two studies: first, a literature review of anticipated California and global technological and industry developments and of workforce surveys and of training needs identified in various studies; and second, on a Time Structures survey of future training needs of California biotechnology firms.

California Biotechnology Job Growth Means Many Training Opportunities
Today, US biotechnology firms employ between an estimated 146,000 to more than 187,000 workers. By 2015, the industry may employ as many as 250,000 or more, particularly if the specialized research identified below takes off. The job multiplier is about 1.9 for biotechnology, meaning that almost two additional jobs result from every biotechnology job created. US Dept of Labor projects that between 2002 and 2012, US employment in the Life Sciences will grow by18%. Employment is predicted to grow by 19% for biological scientists, 19% for biological technicians, and 23% for workers in pharmaceutical and medicine manufacturing.

The top five occupations projected to grow in California by the Labor Market Information Division, California Employment Development Department, from 2000–2010 are: Bioinformatics Specialist (99%), Scientific Programmer Analyst (59%), Animal Technician (44%), Microbiologist (41%), and Assay Analyst (35%). A total of 43,600 technicians with AA degrees are projected to be needed in 2010, an increase of 17 percent over 2000. An additional 8,100 technician level positions could open up due to separations and internal promotions. These estimates may be conservative given other industry size estimates by independent groups such as the California Health Care Institute, and by Henry Madrid, (a data analyst specialist examining trends).

Job opportunities requiring familiarity with biotechnology industry operations and processes will develop as companies expand and as the supplier and specialized service provider networks grow. These developments offer additional training opportunities for occupations like regulatory specialists, Intellectual Property attorneys, and clinical trials experts.

The report lists a large number of biotechnology industry and cluster related careers, including level of preparation required. Industry new hire skill preferences are identified. Examples of needed basic and intermediate occupational skills and of technical, laboratory, production, bioinformatics and other higher levels skills are provided. Suggestions are made for training management to better retrain skilled workers.

California Biotechnology Industry Growth and Global Competition
Like all manufacturing today, biotechnology is global, involving extended research partnerships, specialized supplies chains, and logistics. Many other countries are

developing highly competitive niche research or manufacturing capabilities. Countries in Europe, Japan, China, Russia/Eastern Europe, Cuba, India, Brazil, Malaysia, Thailand, Korea, Singapore, Israel. Bahrain/Dubai/Middle, South Africa, Canada, and Australia/New Zealand have all established biotechnology clusters. The Asian biotechnology industry is growing rapidly. Global networks will compete with and link these activities to California.

While Biotechnology is growing in the US, it appears to be growing more slowly than in the past and may not show a profit as an industry until 2010 or 2012. On the other hand, the pace of patent applications, and approval of California pharmaceuticals and medical devices has increased. At least 643 new drugs are in the pipeline today. The future issue is how many will actually be manufactured in California.

Mixed signals on manufacturing were detected in the literature review compared to the industry survey. The California Health Care Institute found that "…in 2003, 66% of the surveyed companies grew their manufacturing capacity in California, while 81% expanded manufacturing outside the borders of the California. Over the next two years, 73% of the surveyed companies expect to grow their manufacturing within the state. However 88% anticipate expanding their manufacturing outside of the state."

Biotechnology: Converging Technologies are Creating New Opportunities

A moment's consideration of the biotechnology definition and sectors provided above shows that a convergence of diverse technologies—life sciences, materials sciences like Nanotechnology/MEMS (micro-electronic mechanical systems), and information technology—is taking place. This convergence will produce a unique materials and productivity advantage for California over the next ten to fifteen year. Biotechnology is one technology of a rapidly emerging *group* of technologies that are bringing together a number of previously separated science and production techniques in the state. From this broader perspective, life-science's biologically based engineering represents a collection of technologies that offer multiple life-sciences applications in essentially—by today's way of thinking—non-biologically based industries. This convergence will cause biotechnology workforce training programs to evolve with them.

California Biotechnology Company's Assessment of Future Technologies and Perceptions of Workforce Training Needs

Time Structures interviewed sixteen biotech business executives and seven spokespersons from universities and industry associations. They were interviewed by telephone during autumn 2005, to obtain their perspectives on biotech trends and training needs for the 21st century.

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1) fermentation, 2) bioprocessing, 3) biotransformation and 4) biomanufacturing were ranked as evolving the fastest.

Fastest Moving Technologies

When asked to evaluate the rate of market development for 19 biotechnologies: 1) fermentation, 2) bioprocessing, 3) biotransformation and 4) biomanufacturing were ranked as evolving the fastest. These market-related technologies are expected to experience significant change within the next one to three years.

Five other market related technologies are expected to undergo similar but slower spurts of growth: 1) advanced drug delivery systems, 2) drug design, 3) culture and manipulation of cells, stem cells, tissues and embryos, 4) diagnostic tests, and 5) nanotechnology.

Protein extraction, purification and separation technologies were the most popular with business respondents. Significant market change—perhaps based on new product development—is expected within the next 1 to 5 years. Markets for cell receptors, cell signaling and signaling pheromone technologies are expected to experience the same rate of growth.

Market change for DNA recombination, DNA sequencing and DNA amplification technologies may be slower due to their maturity as a technology.

Three other technologies were given mixed reviews on their ability to influence market change, partly because of maturity assessments and partly because of ambiguity about whether the question referred to research or application: Peptide and protein sequencing and synthesis; microbiology, virology and microbial ecology; and combinatorial chemistry, 3D molecular modeling, and structural biology all may experience significant long-term change within one to ten years.

While the market may be hot for some of these technologies, public policy issues are viewed as obstructions because of regulatory issues and problems with coordinating different levels of government.

The most requested "skills" are knowledge of biochemistry, molecular biology, cloning and cell culture.

Technical Workforce Skill Needs

Because the industry is rapidly changing in technology and applications, there is a continuing need for more training in the basics. The most requested "skills" are knowledge of biochemistry, molecular biology, cloning and cell culture. The second most requested skill has to do with the ability to perform basic research. Lab protocols and techniques are needed (such as aseptic techniques), and knowledge of instrumentation and data analysis. Most employers provide in-house training on procedures specific to their activities, but a foundation in practical laboratory procedures is necessary (more detail on skill occupational projections, skills, and business training needs are developed from other surveys and materials and are provided in the report).

Continuing Global Biotechnology Specialization and Diversity will Challenge the Biotechnology Initiative to be Flexible and Agile

Time Structures' survey identified the need to strengthen existing skills consistent with basic research and manufacturing requirements. Businesses have also identified significant new and evolving technologies that will affect market position. The broader look at industry provided by the literature review indicates that a number of new enabling technologies are on the horizon and are expected to grow in influence. These converging technologies—nanotechnology, information technology, MEMS, and advanced manufacturing technologies—will revolutionize existing industries and produce new sectors and jobs in the next five to fifteen years.

The difficulty is that it is unclear how well California is actually positioned to take advantage of these developments even though many of these technologies are already highly developed in the state. "First move" advantage could be achieved by other developed nations in Europe or East Asia. "Niche" competition from smaller nations could winnow away individual sectors. This suggests a strong need for the Applied Biological Technologies Initiative to monitor promising convergent technology sectors and to firmly reach out to emerging industry sectors.

Biotechnology Workforce Training Opportunities for California's Community Colleges

California biotechnology businesses and association expressed a desire in the Time Structures survey to have the community colleges communicate and collaborate with them, to keep up with current trends through market and trend research, and to continuously update core programs. Many used the survey opportunity to give accolades to the community colleges saying that the colleges should keep doing what they are already doing because it is being done well and meeting industry needs. Industry also is willing to serve as a resource for training both students and teachers by providing facilities. Many talked about developing internships. They expressed an interest in having trained students introduced to them. Some spoke to the issue of improving the Community Colleges' course content by strengthening practical lab experience. Interviewees also expressed interest in improving their business' customer service.

Research for the Biotechnology and other Economic and Workforce Development Programs indicates that it is important to resolve various Community College and system wide policy issues that limit Biotechnology's and other initiative's ability to hire instructors, to fund successful centers, and to disburse and/or integrate key programs amongst campuses. Specific options that could improve the Economic and Workforce Development Program's operations include the following suggestions: 1) complete the removal of the statutory sunset clause from the California Community College's Economic and Workforce Development Program's enabling legislation; 2) that the Economic and Workforce Development Program create or facilitate a strategy that will satisfy the Community College system, making possible the rapid hiring of qualified part-time and full-time instructors for the Centers by examining limitations imposed by the "25%/75%" rule on program growth; and 3) that the Economic and Workforce Development Program investigate a strategy and develop options for a plan to facilitate movement of mature programs onto campus throughout the system without losing their essential capacity to generate new curricula in response to changing industry and workforce needs." (Koehler and Koehler-Jones, 2006)

The only constant is change—learn to embrace it.

"The Only Constant Is Change—Learn To Embrace It"

—Malcolm W. Graham

We have an opportunity to embrace these changes. Global development affects workers and skills needed in the workplace, which in turn affect how well this and other nations compete and thrive. The United States is no longer outpacing its competitors as it did 40 to 50 years ago. Global competition is nipping at US heels. The Net generation expects good wages, which may be in jeopardy due to lower cost of living in other countries. Currently, many workers do not have the skills to meet the new needs in the workplace, and incoming workers often do not recognize the need for innovation as the driver for the US economy. They also may not realize that such innovation relies on workers having scientific, mathematical and technical skills, alongside workplace competency skills. The California Community College Economic and Workforce Development Program (http://www.cccewd.net/) is one attempt in California to gather together these facts and apply them to meeting workforce needs for the biotechnology industry.

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MARY PAT HUXLEY coordinates and provides leadership to build the California Community College System's capacity to deliver education, technical skills, training and services appropriate to biotechnology-related businesses for their incoming and current employees. Her experience includes: five years as state director; fourteen years as a Ventura College adjunct instructor in biology; and ten years as a visiting research scientist with the Naval Facilities Engineering Service Center. She has a BA degree in biology from University of California San Diego, an MSc in genetics from the University of Dublin, Trinity College, and a doctorate in organization change from Pepperdine University.

Dr. Huxley created the non-profit Venture Coast Biotechnology Initiative and served two years as its Executive Director. She is a member of the American Association for the Advancement of Science, Sigma Xi, the Biotechnology Industry Organization, the National Agricultural Biotechnology Council, and the Academy of Management. She serves on the Advisory Committee for the Career Ladders Project, the Outreach and Education Committee of the Biotechnology Industry Organization, the Workforce Committee of BayBio, the Advisory Committee for Community Colleges for the Biotechnology Institute in Arlington, Virginia, and the Advisory Committee for Biotechnology Workforce of the California Labor and Workforce Development Agency.

Translating Discovery Research into Commercial Products

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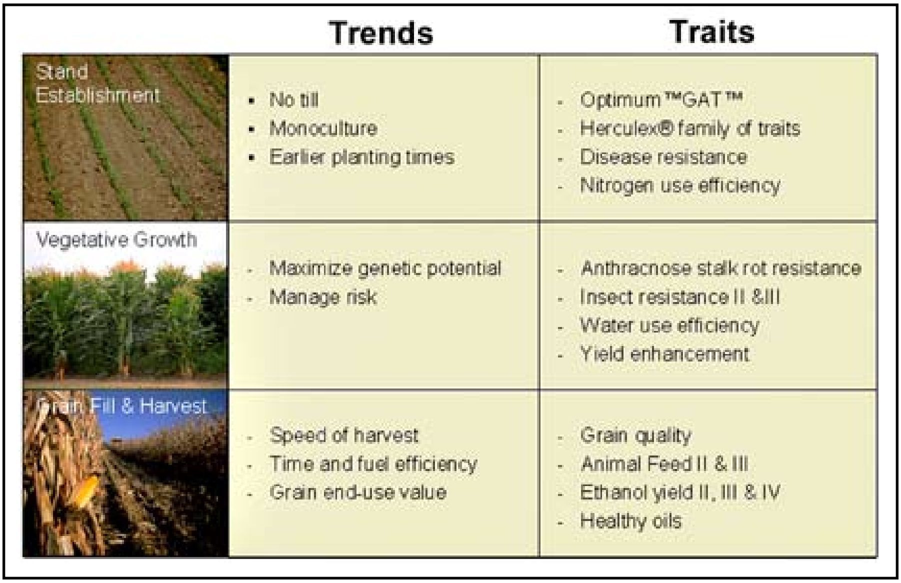
DuPont's Agriculture and Nutrition Platform consists of three business units: Pioneer Hi-Bred International, DuPont Crop Protection Products, and Solae, an alliance between DuPont and Bunge Limited formed to develop and market nutritious soy-protein products. These businesses develop products for customers all along the agricultural value chain, from seed- and crop-protection chemical inputs for growers, to novel grain traits for food, feed and fuel processors, to more healthy and nutritious food products for consumers. The platform is supported by two R&D organizations. The focus here is on Crop Genetics R&D, aimed at the development of biotechnology traits.

Increased Demands on Agriculture

Growing needs for biobased, renewable fuels and materials will place a greater demand on agricultural productivity leading to the adoption of more intensive agricultural practices. To be successful under such conditions, farmers will require a suite of traits that protects crops from abiotic and biotic stresses, especially if economic conditions benefit mono-cropping practices. Trait combinations will be needed that protect crops from disease and help minimize risk to growers, that enhance crop productivity and genetic gain and that increase the end-use value of the harvested grain. Expression of such traits will be required at appropriate stages of plant growth and development to maximize effectiveness.

Our pipeline includes Optimum GAT, which provides new weed-control opportunities, the Herculex insect-control traits, increased nutrient-use efficiency, grain traits and drought tolerance.



	Trends	Traits
Stand Establishment	• No till • Monoculture • Earlier planting times	- Optimum™GAT™ - Herculex® family of traits - Disease resistance - Nitrogen use efficiency
Vegetative Growth	- Maximize genetic potential - Manage risk	- Anthracnose stalk rot resistance - Insect resistance II &III - Water use efficiency - Yield enhancement
Grain Fill & Harvest	- Speed of harvest - Time and fuel efficiency - Grain end-use value	- Grain quality - Animal Feed II & III - Ethanol yield II, III & IV - Healthy oils

Figure 1. Intensive agricultural production will demand traits for increased agricultural productivity.

Figure 1 shows traits that will provide growers with new and better options for weed and insect control. Our pipeline is robust and contains second- and third-generation traits that will follow in the marketplace after initial trait concepts are commercialized. Some specific examples include Optimum GAT, a trait that provides new weed-control opportunities and the Herculex insect-control family of traits. Other longer-term traits include disease resistance from transgenic and native sources, traits that increase nutrient-use efficiency, grain traits for food, feed and fuel uses and drought tolerance.

Complementary Approaches to Trait Development

Currently we employ two complementary technical paths to develop traits: a conventional transgenic plant approach and the use of marker-assisted breeding to identify and stack genetically complex, native-trait loci. We also use map-based cloning strategies to identify the genes and pathways involved in conditioning such complex traits. Often stacking both transgenic and native traits is required in order to achieve a product concept that meets customer needs. For example, to develop improved feed traits, we are exploiting natural variations for certain grain components—such as increased digestibility—and

Successful product development demands that traits are bred into the most elite, high-yielding germplasm.

combining these loci with transgenic approaches that achieve a more balanced amino acid composition in the grain. Successful product development also demands that traits are bred into the most elite, high-yielding germplasm, and the use of molecular markers and other technologies like double haploids can be used in conjunction with contra-seasonal seed production to accelerate trait integration and breeding timelines.

Robust Project Management

In addition to a strong discovery platform, product development requires a robust project-management system to ensure that resources are allocated optimally to advance traits rapidly through the product-development timeline. At Pioneer, we use a process called Stages and Gateways to provide a framework for project-advancement decisions. It is a gated discovery process that provides defined technical and commercial criteria that must be achieved for projects to move toward commercial development. Projects that have achieved proof-of-concept, have a clear intellectual property protection strategy, and have confirmed phenotypes in field and greenhouse trials advance to Phase 3 or Advanced Development where field and laboratory data are assembled and submitted for regulatory approval, and extensive field-efficacy and breeding trials are conducted. Advancement to Phase 3 signals an organizational commitment to commercialize a product and requires a significant increase in dedicated resources. New products with novel end-use applications require extensive product testing to confirm their value in-use and to quantify specific customer benefits. Such early application testing also provides data to support communications about consumer benefits.

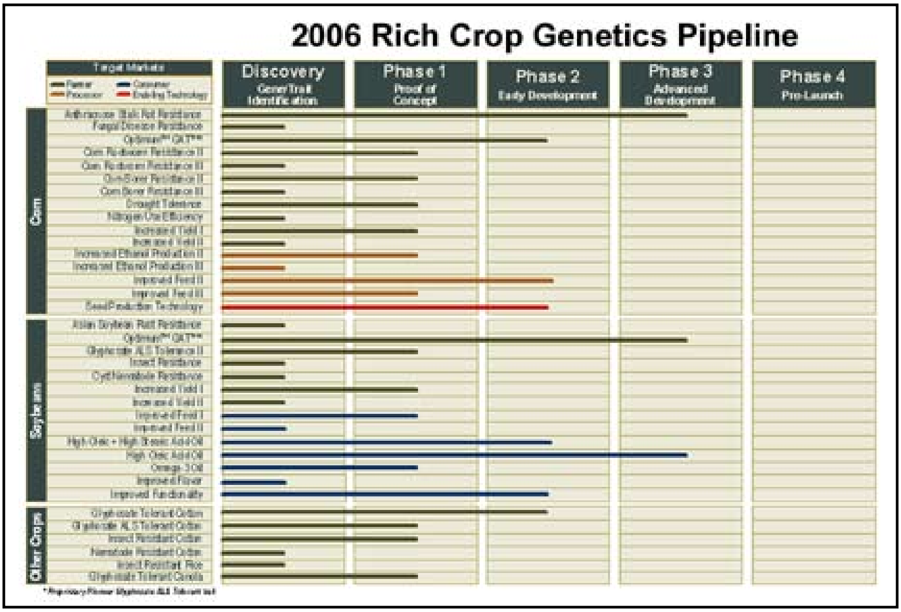


Figure 2. Pipeline of biotechnology traits.

Product Pipeline

As we look at our trait pipeline (Figure 2), we can see a shift from traits conditioned by single genes, such as insect or herbicide resistance, to traits where combinations of multiple genetic loci and/or several transgenes are required to achieve product specifications. In some cases, several genes are required to introduce new pathway branches to produce beneficial seed-oil compositions, such as in the production of long chain omega-3 fatty acids in soybeans. As more success is achieved in producing such products with clear consumer health benefits, more education will be required to achieve consumer acceptance of these products.

Production of health-promoting omega-3 fatty acids in soybeans represents a technical accomplishment achieved by introducing five to seven new biochemical steps.

Figure 3 shows our family of healthy oil products. On the market today is a non-transgenic, low-linolenic soybean oil product used in food-ingredient applications to reduce the amount of trans-fatty acids in the diet. This product will be followed in the market by a high oleic acid soybean product produced by reducing the amount of delta-12 de-

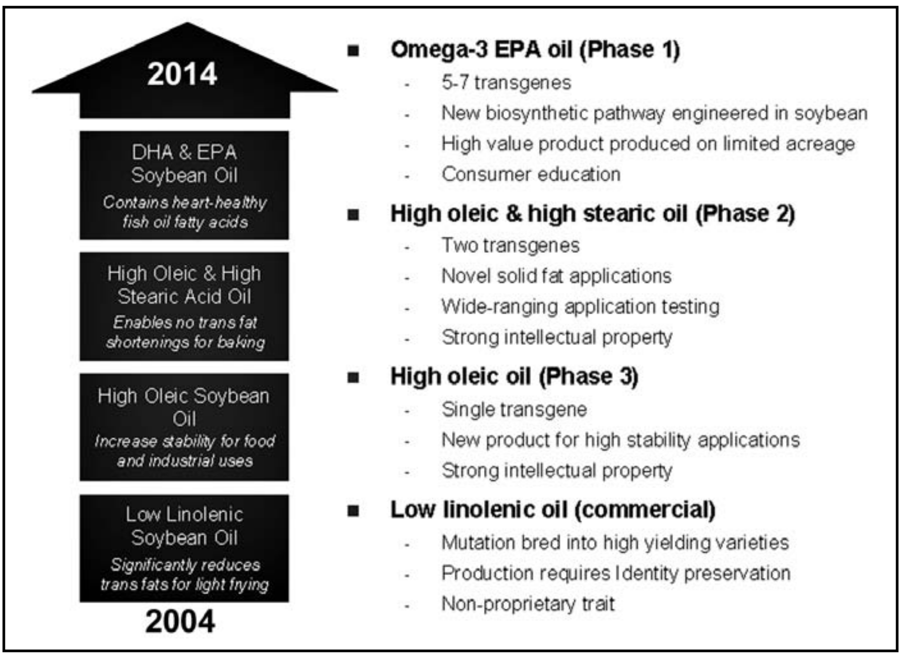


Figure 3. Soybean oil product pipeline.

saturase in the seed and preventing the conversion of oleic acid to linoleic acid. High oleic soybean oil is extremely stable, eliminating the need for hydrogenation. Combinations of high oleic acid and high stearic acid traits provide novel, healthy oils for solid-fat food applications. Production of health-promoting omega-3 fatty acids in soybeans represents a technical accomplishment achieved by introducing five to seven new biochemical steps required for the production of long-chain omega-3 fatty acids. This trait has achieved the proof-of-concept milestone in our pipeline. The commercialization of such a complex trait will require more investment of resources to ensure trait stability, agronomic performance and public acceptance than, for example, the introduction of second- and third-generation insect-resistance traits, where first-generation products already enjoy wide commercial acceptance.

In Conclusion

Several key components are required to translate discovery research into successful biotechnology-based products: a robust, technology-enhanced trait-discovery platform; a rigorous process for advancing products through the product-development process, increasing the probability of technical and commercial success at each step; a strong and experienced regulatory sciences program that provides high-quality data for agency approval; and a clear understanding of unmet customer needs.

Richard Broglie is director for global R&D strategy for Crop Genetics Research and Development, which discovers and develops products primarily for DuPont's Pioneer Hi-Bred International seed-business unit. He received his PhD in microbiology from Rutgers University and served as both postdoctoral fellow and assistant professor in the Laboratory of Plant Molecular Biology at The Rockefeller University before joining DuPont in 1985.

Dr. Broglie has held a number of research-leadership positions at DuPont, and has made significant contributions toward the discovery of traits for modified soybean and canola oils and disease resistance in corn, soybean, wheat and rice. He has served on the board of directors of InterMountain Canola, a limited partnership between DuPont and DNAP, and as business development manager linking internal research programs with strategic business partnerships.

In his present role, Broglie has responsiblity for developing and implementing R&D strategies in India and China to access talent globally and to develop products for emerging markets in Southeast Asia.

Technological Ethics in University-Industry Partnerships: The Best of Both Worlds?

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Broadly conceived, ethics is the study and review of whether any given practice is good or bad, right or wrong, justifiable or unjustifiable in a given set of circumstances. NABC 18 has explored a number of practices for linking scientific research with private enterprise. The fact that conferences are being held to explore ways to do this suggests that somebody thinks that this is a good thing to do. An ethical analysis of establishing closer ties between academic researchers and commercial technology providers needs to delve into those reasons and subject them to some critical discussion.

The current opinion and analysis on whether such partnerships are justifiable tends to make one of two framing assumptions. On one side, there is the view that society needs more efficient ways to deliver the benefits of publicly funded research to the public that funded it. Here, better (which usually means more extensive) linkages between academics and industry are promoted with the idea that for-profit firms are best able to make scientific discovery available for public use and consumption. This point of view led to the passage of the Bayh-Dole Act (PL 96-517) in 1980 and has been articulated explicitly as the basis for linking university research to state and national economic development.

On the other side is the view that science should be separated from profit-seeking technology development. Some people who hold this view prefer socialist political schemes and presume that pursuit of profit is intrinsically problematic. Others who make this criticism make one of two arguments to support the more subtle view that while capitalism is a legitimate form of society, some aspects of science should be isolated from capital. One argument stresses the public's need for unbiased sources of information and expertise in order to bring about democratic governance, and interprets links between public-sector research and venture-capital investment as compromising the ability of university, government and non-profit scientific research to fill this need (Krimsky, 2003). The other argument stresses the need for public disclosure and reproducibility within the research process itself. This view suggests that pressures to seek commercializable results and the secrecy that accompanies proprietary technology will ultimately lead to the weakening of science as a knowledge-seeking social institution (Busch *et al.*, 1991).

Technological ethics are today better served in the private sector than in the universities.

While I am certainly willing to undertake the task of pursuing these assumptions to some degree, I want to suggest a somewhat different way to focus our deliberations. Let me begin with a bold conjecture, one for which I can offer no data and that will be contrary to the biases of many people: Technological ethics are today better served in the private sector than in the universities. If my conjecture is correct, university/industry partnerships could have the result of improving the capacity for university-based science to address ethical issues, if they bring some of the norms and practices that are commonplace in the private sector into the university. Or they could have the result of transferring the relatively weak performance of university science to the private sector. While we can hope for the better outcome, my conjecture is that university/industry partnerships are likely to produce the worse one. But first I must say a bit more about what I mean by technological ethics.

What Is Technological Ethics?

Although there is no widespread consensus on what technological ethics involves, I am thinking about proposals made by the philosopher Hans Jonas in the 1970s and 1980s. Jonas began by making two very straightforward observations. First, he noted that the nature, rate and scope of technological innovation had been gradually increasing for at least 200 years. By the time that Jonas wrote his original German text some 30 years ago, it was no longer plausible to think that changes in technology could be treated as something like an act of God: relatively rare and beyond the ability of human beings to contemplate. Instead, Jonas argued that that technology had reached a point where humanity *could* and *should* engage in deliberate choices about the future direction that technical innovation should take (Jonas, 1984).

Jonas was not suggesting that we have the ability to predict the future in detail, nor was he suggesting that we could determine the likely social or ecological impacts that would follow from discoveries in basic science. Instead, he was saying that cumulative experience with technical change and our increasing ability to model and forecast social and ecological trends establish a basis for social decision-making about which specific technologies to develop and implement, as well as how to regulate technological risk. I have often heard scientists object to this proposal by saying that it is just not possible to project the consequences of a scientific discovery. But Jonas was not claiming an ability to foresee the consequences of technological innovation that exceeds foresight commonly exercised by private firms and venture capitalists, who routinely *do* make decisions about which technologies to develop and implement.

If there is anything truly controversial in Jonas's observation, it is that there should be *social* decision-making about the ends-in-view that guide such choices. This is a point that I will, of necessity, leave somewhat undeveloped in the balance of my remarks. I accept the validity of allowing capital markets to suffice for some forms of social decision-making. Nevertheless, I also endorse the need for deliberative public and quasi-public forums in which constituencies excluded from capital markets can have a voice. Further specification of the means for social decision-making is one of the key problems in technological ethics.

Jonas's second observation concerns the nature of ethics. He claims that our current understanding of responsibility remains trapped in the village mentality of the eighteenth century. I believe that he has several related points in mind. Most importantly, we work with a conception of moral agency that presumes individually initiated actions having impacts that are limited to village-sized temporal and spatial scales. In fact, the acts that need to be brought under an ethic of responsibility are seldom initiated by a single individual. They are the cumulative and corporate result of many people acting in organized fashion, often under the guidance of corporate decision-making structures. When I use the word "corporate" here, I do not necessarily mean multi-national or even business corporations. The point calls attention to organized, coordinated and at least partially controllable forms of collective action, as distinct from mob rule or the purely coincidental cumulative consequences of people acting in haphazard fashion (French, 1984).

Modern technology development may not be orchestrated or bureaucratically governed in its details, but it is not haphazard. Practices of peer review in the applied sciences, tenure and promotion in universities, and grant-making by government and foundations join with somewhat bureaucratically controlled forms of R&D to generate a truly corporate form of action. Furthermore, these corporate acts involve the development and dissemination of new technology with spatial consequences that are global, affecting many people who are entirely unknown and even unknowable to the actors. As such, a conception of ethics that is grounded in personal loyalties based on face-to-face reciprocity established among neighbors and townsmen is increasingly inadequate. In addition, effects may be cumulative and latent, affecting people in the distant future. Traditional ethics was keyed to forms of action where impacts would be felt by people known to one another within a time-frame that allowed one to link cause and effect in rather intuitive fashion.

Jonas's point was that our working notion of ethical responsibility is simply out of sync with this new reality. While people of today may have the same desire to be ethically responsible as people in the past, the functional outcome of acting according to norms that emphasize personal loyalty and reciprocity is not the same as what it was in the past.

On the one hand, technological ethics is the organized and thoughtful exercise of foresight and deliberative choice in selecting projects for applied science and technical innovation. This involves utilizing the limited but hardly inconsequential powers of foresight we possess in an effort to innovate and validate new ethical understandings capable of guiding our technology. On the other hand, technological ethics is an effort in public scholarship aimed at understanding and addressing the conceptual, organizational and practical obstacles encountered in making such choices.

As an academic philosopher, I see myself working in this tradition of public scholarship. While predictive power is clearly one aspect of technological ethics, the philosophical piece involves our understanding of fairly basic ideas such as "action," "responsibility," and "democracy," as well as a more explicitly articulated vision of the future that we collectively desire. Different conceptualizations of these basic elements can lead to striking differences in the way that one characterizes risk and risk-management. As such, there is always opportunity to discuss and debate how risks should be characterized in a given case, and such debates have been the main substance of technological ethics for agricultural biotechnology, (Thompson, 1997, 2003).

Scientists, engineers and business leaders working in the private sector have done a much better job of implementing technological ethics as a practical activity than have scientists, engineers and administrators in universities and public-sector laboratories.

Ethics in Industry and University Settings

My bold conjecture is that scientists, engineers and business leaders working in the private sector have done a much better job of implementing technological ethics as a practical activity than have scientists, engineers and administrators in universities and public-sector laboratories. Rather than pretending to have data that support this conjecture, I will make a brief conceptual argument to illustrate why I think this is the case. One element of this argument stresses the nature of private enterprise and the working environment created within for-profit firms, while the other describes the milieu and culture of university science and engineering departments.

The argument in favor of thinking that people in the private sector do in fact undertake the practical deliberations involved in technological ethics to some degree is fairly simple. First, they are human beings and as such are motivated by the same desires to act ethically and to be seen favorably as all human beings. Historically, people in business have aimed to market products and services that people want and need, and to encourage growth and prosperity in the communities in which they do business and reside. In short, they *intend* their business activities to have effects in these communities, and such intentions are a locus of moral responsibility. Second, the need to gain market acceptance for the goods and services that a business offers, and to have a reputation for quality and reliability, provides a reinforcing incentive for profit-seeking firms to act in an ethical manner. I see no reason to think that people engaged in business are particularly inclined to dismiss or belittle ethical responsibilities simply because they are in business, and every reason to think that they would like to conduct their business affairs, including and especially those involving technical innovations, in an ethically responsible manner.

There are, of course, scam operations that are completely unethical, and they tarnish the very idea of business, but it is important to note that scams are not really business activities at all. Well known structural elements in innovation and profit-seeking enterprise can constrain the ability of legitimate businesses to fulfill ideals of technological ethics, as well. The most important structural tension for present purposes arises when a product or manufacturing process is seen to have unwanted health or environmental impacts well into the cycle of product development, sometimes long after products have been marketed and utilized by the public. In such situations, the economic incentive switches from being ethical to being secretive and avoiding losses. The chemical and pharmaceutical industries have been especially plagued by well-publicized incidents from thalidomide and Love Canal to Erin Brockovich and Vioxx®. Such incidents reinforce public cynicism about the private sector's commitment to ethics, but they also reinforce the incentives for technological ethics early in the cycle of product development.

As such, I am content to leave my argument with the claim that for-profit enterprises have incentives to engage in technological ethics and that the people working in these firms are motivated to act ethically. I do believe that the private sector has not been as assiduous in utilizing or encouraging public scholarship in technological ethics as it should be, mainly because there is an attempt to rely on the kind of village ethics that Jonas critiques so ably. But that is a matter to which I will return later. The other point that I must make to establish my larger claim is that, quite contrary to those who see university-based science as contributing to democratic governance of science and technology, university science departments have actually not been very good places to pursue technological ethics at all.

University scientists do not really intend that their research will have immediate impacts on the communities in which they work and reside.

The conceptual argument for this claim is that the incentives in university science and engineering departments are organized around publications, grantsmanship and patents. While university scientists are human beings, they do *not* really intend that their research will have immediate impacts on the communities in which they work and reside, and it is very easy for them to assume that any ethical questions associated with their research will be dealt with by someone else at some other time. These basic incentives of university research have been reinforced by a positivist philosophy of science which holds that statements about values or ethics cannot be subjected to the same standards of validity as statements reporting data or relationships among data, and, as such, have no place in the professional activities of the working scientist. While the hold that this philosophy has over working scientists has weakened significantly over the last 25 years, it continues to provide an obstacle to the practical discussions and deliberations characteristic of technological ethics within the environment of academic science departments, and especially within the training and education of scientists.

Paul Rabinow's study of the biotechnology industry, *Making PCR*, shows that many molecular biologists in the 1980s and 1990s chose industry careers over academic careers precisely because they saw university science departments as incompatible with their values and resistant to change. The subjects interviewed for this study describe academic science as competitive and obsessed with egotistic gratification and career advancement. They chose industry because the work environment was more cooperative and was dedicated to science in pursuit of environmental and public-health values they held dear. Rabinow's informants also describe biotechnology companies as more accepting of women and minorities than were university science departments (Rabinow, 1996).

There are, of course, many exceptions to these generalizations among individual scientists. I have personally found many molecular biologists and agricultural scientists working in academic settings to be deeply interested in my work on the ethics of agricultural biotechnology, and I have learned a great deal from those individuals who have taken the time to read and criticize my work. Nevertheless, as Robert Zimdahl's new book, *Agriculture's Ethical Horizon*, makes clear, positivist values are still quite prevalent in agricultural science departments. Debate, discussion, teaching and thoughtful deliberation on the ethical dimensions of agricultural science and technology are still the exception to the rule in agricultural universities and government research laboratories (Zimdahl, 2006).

As such, I reiterate my claim that technological ethics are better established in private industry than in academic science. This is not to say, however, that the mode of practice for technological ethics in the biotechnology industry is beyond criticism, nor to imply that university-based technological ethics is wholly inferior. In fact, there are interesting complementarities between the weaknesses in private-sector technological ethics and the strengths of academic approaches. Respective weakness and strength in both cases relates to the role of scholarship in technological ethics, a practice that currently exists primarily in university ethics centers and social science departments, and that is poorly utilized by even industry decision makers who are well-motivated and have economic incentives to understand the likely impacts of and public receptivity to their technologies.

Toward Partnership in Ethics?

University-based scholarship in technological ethics has two important features not typically present in industry settings. One is simply the luxury of expertise. Scholars in technological ethics are professionally devoted to understanding the normative, social and theoretical issues involved in effectively anticipating and understanding the social, economic, cultural and ethical significance of innovation and technical change. They can bring a variety of empirical, comparative and analytic methods to this task. Ironically, the cultivation of expertise can have unfortunate consequences, as academic scholars come to rely on complex and jargon-ridden theoretical models that make it difficult for them to extend the fruits of their studies to an audience with more practical and immediate concerns in mind. In addition, scholars of technological ethics are always at least one step removed from actual decision-making in research and development settings. This distance can be the source of many errors and irrelevancies that make this work less useful to practical application than it might otherwise be. Nevertheless, I believe that those of us who conduct scholarship on technological ethics have learned a few things that would be of use in conducting practical ethical inquiries about which technologies to develop and what applications of science to pursue.

One might argue that the findings of the scholarly community are available to industry on a consulting basis, and this is true. In point of fact, they are freely available as published materials, too, but consulting arrangements may be preferable to decision-makers who are already strapped for time. Here, however, the second limitation of industry-based technological ethics comes to the fore, and it is a limitation that lies at the very heart of the public/private divide. Scholarship on technological ethics is effective to the extent that it is public, meaning that it is freely available for peer commentary and critique, but also that it both is and is seen as a non-strategic activity aimed solely at disclosing the ethics researcher's best guess at ethically correct standards for development, dissemination, adaptation and regulation of new technology. Public criticism and debate over this guess is essential to the method, and this criticism must also be motivated solely by the goal of agreement on the best and ideally operative standards.

While private industry can conduct exercises in ethical deliberation under such idealized conditions as a practice intended to inform their internal decision-making, there are sound business reasons why public disclosure of this process will, on occasion, be constrained by considerations of legal and business strategy. Because everyone understands this, statements and disclosures made by private industry are regarded quite properly as strategic, as intended to manipulate the reaction and posture of others, rather than as trying to articulate the values and reasoning of company decision makers. Only a public activity independent of practical decision-making can provide the environment for legitimate inquiry into technological ethics.

As such, broad public competence in technological ethics, including familiarity with the terms and problems of R&D policy and the socio-cultural significance of technology and technical change depends on the existence of a non-strategic body of scholarship. Such public competence is needed if we are to realize Jonas's goal of social decision-making on technical means. Given currently existing social institutions, universities remain the most likely home for such idealized types of public inquiry, despite the fact that university-based scholarship is vulnerable to the distorting influences I have already mentioned. More intimate and effective insight into ongoing industry problems and practices would clearly strengthen scholarly attempts to understand and respond to technical change. Better communication between scholars and practical decision-makers could improve decision-making. And now it is possible to return at last to the main theme: university/industry partnerships, and the development of innovative institutional settings for scientific work that bridges commercial and academic cultures.

We might hope that these new ventures would become laboratories for technological ethics, places where the complementary strengths of practical ethics as practiced within industry and scholarly ethics as practiced within universities might be joined.

Given what I have said so far, we might hope that these new ventures would become laboratories for technological ethics, places where the complementary strengths of practical ethics as practiced within industry and scholarly ethics as practiced within universities might be joined, or at least might come close enough together for practitioners on both sides of the public/private divide to peer over the fence and derive mutual benefit. This would indeed be the best of both worlds for technological ethics in university/industry partnerships. It will not happen automatically, however, and will require careful thought and planning as to how the social science and humanities disciplines so critical to scholarship on technological ethics might be integrated into partnership activities.

What is more likely, I fear, is the opposite result, something more like the worst of both worlds. The scientific culture of the academic world that places so little value on reflective deliberation into the ethics of science and technology will dominate the partnership. The imprimatur of university research will substitute for the exercise of technological ethics that currently exists in the private sector, and the industry culture of strategic thinking will pick up the ball after key ethical commitments have been thoughtlessly made. The result will be a series of technical innovations even less subjected to deliberative ethical review and foresight than those of the past. These technologies have the potential to move so quickly into development and regulatory review that no one will have any opportunity to debate their likely impact or acceptability. What is more, as the public becomes wise to the overriding strategic ambitions of these partnerships, the fears of critics who worry that industry links will undermine confidence in science will be realized.

This pessimistic scenario is not the inevitable result of university/industry partnerships, and it may not even be the most likely one. What we will probably get is something more like the *status quo*, with university scientists acting more like businessmen, which in this case is a good thing because it means that there will be some exercise of ethical foresight. Researchers such as me, however, will remain on the margins, or more literally back on the main campus, where we will spend most of our time talking to one another. While there are some more hopeful signs on the horizon—my invitation to speak at this conference being one of them—we will have to wait and see what the individuals who execute these partnering activities actually do.

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Dr. Thompson published the first book-length philosophical treatment of agricultural biotechnology in 1997, and has traveled the world speaking on the subject. In addition to philosophical outlets, his work on biotechnology has appeared in technical journals including *Plant Physiology, The Journal of Animal Science, Bioscience,* and *Cahiers d'Economie et Sociologie Rurales.* He serves on the US National Research Council's Agricultural Biotechnology Advisory Council and on the Science and Industry Advisory Committee for Genome Canada.

Thompson has published extensively on the environmental and social significance of agriculture. His 1992 book (with four coauthors) on US agricultural policy, *Sacred Cows and Hot Potatoes*, won the American Agricultural Economics Association Award for Excellence in Communication.

Bridging the Gap: From Laboratory to Commercial Product

Q&A

Moderator: Anthony Shelton
Cornell University/New York State Agriculture Experiment Station
Ithaca/Geneva, NY

Tony Shelton: We've covered a lot of ground today but we now have the opportunity to ask some penetrating questions of the speakers.

Peter Welters (Phytowelt): I have a question for Mike Adang regarding your BtBooster. The beauty of the *Bt* toxin is that it's very specific because it has a specific binding site in the gut of insect. By delivering binding sites with your BtBooster, will specificity be compromised? Will there be higher toxicity for non-target insects or even mammals?

Mike Adang (University of Georgia): The question is, essentially: does BtBooster affect insect host-range? Well, we haven't seen a change of the BtBooster toxin binding to the insect mid-gut in specificity. The *Bt* toxin still kills the same set of insects and if you have a level of toxin that kills maybe 10% to 15% of the insects, it kills them more rapidly. It doesn't make a caterpillar-active toxin kill a beetle or a mosquito. We haven't looked yet at other lacewings for non-target effects. And we haven't done any mammalian tests. They will be done, but I would be very surprised if it has any effect like that, because it doesn't seem to be altering the basic toxin mode of action requiring receptors, things like that.

Ralph Hardy (National Agricultural Biotechnology Council): I want to look at this from the industry side. I have a couple questions. One: what does industry expect from the public-sector research—ARS, CSREES, university research? And two: when industry is presented technologies that come from within and from without, how do you make a decision on which to pursue? How do you manage that?

We don't have the "not-invented-here" syndrome anymore.

Richard Broglie (DuPont): Your first question is, what do we expect from the public sector? Certainly, because of what I talked about in the investments and the costs associated with developing the products that we have in our pipeline now, there are plenty of opportunities to look for new products to come into that log jam. The log jam is a good thing if you've got lots of logs coming into that so you can make the right choices, and certainly we know that we can't do everything internally so we are looking for partnerships. We have a number of partnerships with both small biotech companies as well as various academic institutions. The key thing is looking for new traits to come in at that early discovery stage. And your second question: we haven't come across that in too many instances. If you have something internally it's more efficient to build on that because you've already made the investment rather than bringing in something that would be duplicative, let's say, if it was developed externally. But more often than not they are complementary technologies and they provide maybe a first or second-generation product. It's like complementing what we already have in place, which would be probably a more favorable situation to looking at something that was developed externally. We don't have the "not-invented-here" syndrome anymore. We certainly need to continue bringing new things into our pipeline—the recent acquisition of Verdia, for example.

Wim Jongen (Wageningen Business Generator): May I go to the other side of the story? It seems now that universities also have the ambition to bring knowledge to the market, to make science work. We see that with the SBIR funding. One question comes to my mind is: when we talk of that part of the system do we do it coincidentally or do we try to structure it one way or the other or make these ambitions really a structural approach of our way of working?

Bill Goldner (USDA-Small Business Innovation Research Grants Program): I'm not sure that the question came across fully—

Mary Pat Huxley (California Community Colleges): The question is: do we put the structure in universities for ethics and entrepreneurship or let it happen by chance?

Broglie: Let me try to address the entrepreneurship part of that and I'll turn over the ethics part. Something quite obvious, at least to me, is that lots of new ideas are being generated at universities and certainly an important link to making those turn into commercial realities is connecting early on with industrial partners. Incubator facilities are important for providing the opportunity for an academic laboratory to move off into an isolated area to continue to develop a technology. Building links early on—so that it's not just by chance that these things develop—with businesses that can pull technologies into the marketplace, is important.

One of my colleagues at the University of Guelph, Dave Sparling, teaches a course on science entrepreneurship.

Paul Thompson (Michigan State University): One of my colleagues at the University of Guelph, Dave Sparling, teaches a course on science entrepreneurship. He gets a lot of students from the sciences, most of whom conceal the fact that they are taking the course from their major professors. They have to do that. Many of them take it as an overload and don't tell their professors that they are doing so. This reflects differences in the generations. They recognize the need to do this, whereas their major professors see it as time away from the main topic. And I see a little bit of that in ethics, but not quite as much. And let me also say that, in terms of what we are prepared to teach in ethics, it's not like we have a curriculum that's well developed and widely accepted. In fact—speaking of my own discipline—very few of the philosophy people who are interested in technology and technological ethics are at what are considered to be the leading philosophy departments. There is a certain sense in which philosophy is institutionalized such that it allows us to keep working on problems that are 2,000 years old. And nobody expects philosophy departments to do much, but everybody thinks that you've got to have a good one in order to be a respectable university. So there is no reason for a philosophy department at a top university to do technological ethics. That's not where the action is in my discipline. I don't think that most of you would be able to ring up the philosophy department at your institution and necessarily get anything that would be worthwhile.

Milt Zaitlin (Cornell University): A question for Dr. Adang. I used to sit on a committee here at Cornell where we dealt with conflict of interest questions that came up when a professor's company invested in his lab and graduate students were doing research directed at the company's interests. How do you address those kinds of issues?

Adang: During my talk I mentioned that the university has developed a document that addresses some of these issues. The university communicates any concerns to the professor—providing the document and then sitting in a group that reviews it with the professor. Then the professor makes it known to the graduate students and others in the lab where the lines are drawn between what is company-sponsored research versus other publicly funded research. As a policy, I have not had students work directly on company projects with the exception of one graduate student who is a co-inventor of BtBooster technology; he has continued working with this. I have updates with my dean in the college, along with Cliff Baile who is the executive of the company. We have open communication and disclosure of what's going on, what's sponsored by whom and who is doing what within the laboratory. I have no restriction on my people in terms of what they present, *etc.*, to the public. Did I answer your question?

Zaitlin: (inaudible)

Adang: You don't allow the company to actually put projects in the laboratory?

Zaitlin: That's right.

Adang: Yeah, different degrees of policy are in place. There's no "blanket" across the US universities. I had this discussion a couple of weeks ago at a meeting with colleagues from Iowa State, University of Connecticut, University of Kentucky and a couple other places—you might call it an entrepreneurs' club. We talked about the different policies universities have. Maybe there should be a standardized way of addressing this issue in ag colleges and universities.

Bruce McPheron (Pennsylvania State University): Can you look into your crystal ball and give us an assessment of where you think the kind of relationships we are talking about are going? We heard positive information about some federal funding sources within the last month. The *Chronicle of Higher Education* has reported that industry investment in university research has actually declined over the past 3 years. It's taken its first dip in quite a while. What's the trend line here? We talked in the last 2 days about the difficulties of getting venture capital for biotech projects, particularly in agriculture. What do you see the slope of the line of these kinds of relationships being over the next several years?

Increasingly, professors are doing things like copyrighting syllabi—trying to protect intellectual property in something as simple as a course syllabus.

Thompson: This is not my area of research, but I know some people who do work on this. Not just in the biosciences—it's even in the arts and humanities—university faculty are becoming overwhelmingly involved in various kinds of for-profit entrepreneurship activities. It's grown dramatically over the last 20 years. Increasingly there is pressure from faculty at almost all institutions to facilitate this kind of thing. I've seen data from economists and others who study this and there's no suggestion that this trend is abating. You guys talk about patents and in my line of work we talk about copyrights but, increasingly, professors are doing things like copyrighting syllabi—trying to protect intellectual property in something as simple as a course syllabus.

Goldner: There's a lot of room right now for speculation. You asked a very good question. I was on the off campus faculty at Rutgers before I came over to USDA—like what Mike was referring to, a lot depends on the culture of the university that you are working with—whether or not you are encouraged to develop technology, develop relationships. When I was at Rutgers certainly that was strongly encouraged in the department that I was involved with to try to be relevant. I'm in the Cooperative State Research Education Extension Service and we have the National Research Initiative, we have the SBIR program, we have other grant agencies that support grant mechanisms that support all types of university research activities, and the internal discussion that we have is: how can we remain relevant? It's the kind of question that we all need to ask ourselves, whether from the university perspective or the industry perspective. The industry perspective is sort of self-limiting in that if you aren't relevant in industry you are gone. You can see from this meeting the synergies and needs to interact among the academic communities, the government in all its permutations and the private sector. That's certainly very important and when we all start thinking like that we will move a little bit more easily towards that. That's not to say that there isn't a role for research in the university systems outside of industry. I think there is a very, very strong need for that. There is no question about it. A lot of funding goes into basic research, but mission-oriented research is also very important.

We've begun talking about having workshops where we will pull all of the complementary aspects together . . . the funding issues, the research issues, the regulatory aspects.

Rick Brenner (USDA-Agricultural Research Service): The issues of commercial success and economic competitiveness are complicated. That has come out loud and clear over the last few days. These partnerships truly are critical if we are going to succeed in this, whether we are starting with a small operation in Geneva, NY, or any of the 150 university research parks across the nation or even in the federal laboratories. It is complicated, it's complex, but it's also essential that we find some solutions to that. I see our role in part is to help develop these public/private partnerships and that's truly what this is about. None of us individually has all the right pieces. And that includes the funding issues. Some of that can come from the federal sector, but a lot of it isn't going to come from the federal sector. The private sector may want to contribute to that funding, but who's going to manage the risks? Who's going to absorb some of that? That is another federal role. Regulatory issues are also involved. How can we not make all of these a no-go just because the regulatory hurdles are far too high? We've begun talking about having workshops where we will pull all of the complementary aspects together that are needed to really be successful in this and that's going to be the funding issues, the research issues, the regulatory aspects. And where we might have an opportunity to begin looking at that is in the current hot-topic items, is in the energy issues, because every one of us feels the need to be successful at coming up with innovative solutions to be less dependent. I can tell you that in ARS we've been getting a lot more interest from private-sector companies talking about what our research capacities may be to help on some of these more basic research issues. And I'll also tell you that we've had venture-fund people calling us and asking us. We have clients interested in this particular area: "What can you tell us about it?" So, there's

Are the worker bees available? Generally speaking, the answer is "no."

enough interest. The question is, is there enough momentum to take this through? From the energy standpoint, that is going to depend on what the price of the barrel does. From my perspective we are going to move forward. We're going to see more creative measures to bring all of these complementary assets together. One of my concerns is: how do we manage those conflicts of interest, especially in the public sector? There are ways to do it but it will involve networking and getting together and talking about these issues.

Huxley: There is something I want to share before we close. When a company chooses to relocate, the choice of location includes appraisal of whether a ready and well-trained workforce is available. Also, depending on company size, seven to fifteen workers support upper management and/or upper scientific investigators. Of those seven to fifteen people who support each person on the higher level, about 30% are technical. The question then becomes: once the company has an idea, gets first funding, second funding, proof of concept, begins to commercialise, are the worker bees available? Generally speaking, the answer is "no." I want to leave that with the group. It's wonderful to have these ideas, tech transfer, *etc.*, but is it possible to bring the product to market and for the company to grow with the right workforce? In many cases, probably not—not right now anyway. That needs to be looked at.

Banquet Presentation

Knowledge Transfer and Economic Development: The Role of the Engaged University in the Twenty-First Century

Mark Crowell
University of North Carolina
Chapel Hill, NC

I will provide an overview of technology-transfer trends and what is working well and what could and should work better. I will discuss some of the shifts in the economy that translate into a new role for universities in terms of economic development and engagement. "Engagement" is a wonderful term, used increasingly to define the role of land-grant colleges in the twenty-first century, which I will amplify. And I will make some suggestions on how an engaged university should interpret its role analogous to that of land-grants in the nineteenth century. Our role is very much the same today, taking knowledge and translating it into ways that benefit society, improve quality of life and improve well-being and wealth creation for the regions in which we operate. And finally, I want to talk briefly about what my professional group has done to extend this conversation into the area of engagement and public benefit.

In the academic setting, technology transfer is a global business.

AUTM

I've just spent a year as president of the Association of University Technology Managers, an international organization with about 3,500 members, 12% of whom are from outside of North America and 10% are from Canada. The non-North American group is growing at 2½ times the rate of the US group. Clearly, in the academic setting, technology transfer is a global business, like many other aspects covered at this conference.

Bayh-Dole

Technology transfer as we know it in universities started in 1980 with the passage of the Bayh-Dole Act, which was the foundation upon which most of us launched our first activities in the tech-transfer arena. As a result of Bayh-Dole, universities can own intellectual property. Prior to it, we could not. In the past 15 years in particular, technology-licensing offices or technology-transfer offices—TLOs or TTOs—have begun to flourish, and not only at large research universities. They are increasingly present also at regional universities, at relatively small universities, at historically minority universities and in other countries throughout the world. Furthermore, they are dealing not only with patentable inventions but also with innovation and knowledge. It is important to realize that, in addition to transferring patents to industry, research discoveries and innovations made by our faculty and graduate students are being made available for the common good.

TTO Explosion

In the past 5 to 8 years, many countries have adopted similar policy infrastructures for technology transfer, both in large industrialized countries and emerging countries. In 2005 I made about fifteen trips around the world, including with Dr. "Vijay" Vijayaraghavan to India, where we helped launch an Indian Society of Technology Managers.

The growth in emphasis of technology transfer, by every measure that we have, has exploded during this period of time. Clearly, it's an activity that is being embraced. On many of our campuses, particularly younger faculty actually interview TTOs when they are looking at jobs, because they expect this asset to be available to help in their research and translational activities. There has been a large increase in the number of licenses granted and many universities are using their intellectual property to leverage research funding from industry. Such knowledge transfer impinges on industrial development nationally, regionally and locally.

Recent years have seen a rapid increase in number of start-up companies resulting from university research. Interestingly, 75% of them locate near the university. Data show that their ability to sustain themselves is affected by the distance from the lab where the science was done; the closer they locate to the university, the higher the chance of success. Again, this speaks to economic development potential.

Impact on Research

How is this phenomenon affecting how research is done at universities and how research agendas are set? Some studies are examining impact of technology transfer in terms of the research environment, academic issues, and graduate students' progress toward their degrees. We don't have to rely on inferences, suppositions or anecdotes to address these issues. Scholarly research has been done by anthropologists, sociologists and economists. Jerry and Marie Thursby at Emory University and Georgia Tech, Atlanta, tracked a number of laboratories that have increased the numbers of their inventions, in an effort to determine whether the portion of research the PIs are involved with that is classified as "basic" changes over time: as they disclose more inventions that are involved in licensing or start-ups do their research programs and students shift more to applied kinds of research activity? The study was rigorous, and the results, published in Science (Thursby and Thursby, 2003), indicated no increase in the portion of research that was labeled "applied" over a period of time in which the level of patenting activity increased ten-fold in the laboratories under study—in short, good science is still being done for the sake of good science.

Emphasis on Revenue?

But all is not rosy. One of the speakers commented that much of what we've done so far has been focused on driving up revenue. On the other hand, if that is true, then technology transfer has been spectacularly unsuccessful. Comparison of the average university research budget with royalties indicates a 2% return on investment. However, I would argue that this is irrelevant. As an illustration: we just licensed a course for teaching conversational Spanish to healthcare workers in the State of North Carolina, a web-administered course for addressing a tremendously under-served population in terms of their healthcare. We licensed this program to Yale University Press, who are now selling it all over the country. We will make a couple of hundred dollars a year, which will not show on the revenue meter. On the other hand, this is a highly successful technology-transfer story and a good example of why we need to expand the conversation and talk about a lot more than money.

We need to expand the conversation and talk about a lot more than money.

I am concerned that the model for tech transfer that has evolved resulted from early focus on pharmaceuticals and biotechnology and in pharma and biotech exclusive licensing is the rule of the day. They will not invest in drug development if they don't have an exclusive license. As a result, we have probably patented things that we should not; we were probably not as skilled as we are today in ensuring that, when we license a technology to a large pharmaceutical company, we reserve an academic or not-for-profit license to share with other academic laboratories. There are horror stories of important discoveries, *e.g.* research tools, becoming "locked up" and unavailable for use. We are developing new approaches to be more careful and better stewards of our intellectual property, so that as we seek new partnerships for licensing a property we do it in a way that helps to position our partner favorably in the marketplace, but also takes into account that these research tools are in large part paid for with tax dollars and should be available to other scientists who need them.

On a related issue, many of our technologies potentially have application and could impart great benefit to populations in less-developed countries. While maintaining our focus on traditional commercialization pathways in developed countries in our licensing practices, we have often failed to preserve avenues of knowledge transfer where it is needed most. However, many universities in AUTM are addressing that issue by partnering with all kinds of organizations and foundations and working very hard to develop new approaches, new standard license agreements that tend to reserve rights to do both types of licensing and technology transfer.

Land-Grant Role

As university technology-transfer offices have increased in numbers since 1980 with pressure to form start-ups, offer licenses and generate research dollars, technology-transfer offices have evolved to be all things to all people. I tell my staff that no matter what we do, a counterforce always seems to be at work to suggest that something could have been done faster, better, cheaper, generating more money, *etc*. The fact is, we have many different competing aims and priorities for our intellectual property assets; it's our job to be as successful as possible in meeting priorities across the spectrum. However, another component is being added to the tech transfer office. We are being asked to become experts in economic development, forcing us to broaden our horizons even further to help reposition land-grant universities in this field of engagement to continue to articulate a compelling role in the new century.

We are being asked to become experts in economic development,

What's driving this? The economy is shifting and our research programs and disciplines and academic boundaries are shifting similarly. From these new alignments, it does appear that the world really is flat. In a speech in September 2005, I heard the prime minister of Singapore end a speech by saying, "Remember: innovate or die." Perhaps a little startling, but it speaks to the fact that the winners in this new economy—particularly in our society where competition is strong and where we can no longer compete on price—will be those who do great work, who produce great technology. The thing that we have always done well and that we have to continue to do well, is innovate, innovate, innovate. We must feed the research beast and stay ahead of the game, continuing to translate discoveries through technology transfer to help drive economic development.

Mary Walshok, an extension person at UC San Diego, is one of my favorite writers on this subject. In her book, *Knowledge Without Boundaries* (San Francisco: Jossey-Bass, 1995), she was one of the first to talk about the universities' role in the knowledge economy. As economic power shifted from possession of territories or natural resources into generators or possessors of knowledge, she stepped up even in the mid-90s to address where universities, particularly land-grants, are going to be asked to function. Whether we want it or not, we are involved in economic development. It's time not only to acknowledge that, but to step up and embrace it.

Knowledge transfer, technology transfer, should be at the epicenter of an engaged university's activities in this new economy.

The Engaged University

In my opinion, knowledge transfer, technology transfer, should be at the epicenter of an engaged university's activities in this new economy and this new century. The Kellogg Commission defined engagement as the interface for connecting people and communities to supplies of knowledge and research residing in the university for connecting the university with real community problems. By seeing engagement in these terms, and thinking about the assets and resources we have to make this happen it becomes clear how these activities converge and why I argue that knowledge transfer should be at the epicenter.

First of all, we must partner effectively and make sure that our training and our research programs are aligned to the extent appropriate and possible with clusters of industry excellence in our state and our region. And we must be sure that we are smoothing the interface between those two to ensure good communication, back and forth, and that our own planning for our research and training programs is informed by what they say their needs are and not by what we think their needs are.

Technology-transfer offices need to develop. They need to be at the forefront of this activity as these plans are laid to ensure that the research programs connect with business and industry needs. Particularly, we must focus on clusters of excellence within the economy, and try to connect them strategically and carefully with those appropriate sectors in our states and our regions. We need to focus on developing a portal to lower the barriers and reduce the "black-box" factor. We hear often from our industry friends that they love to work with the university, they know we are doing great research, but they are unable to determine what we are doing and they find it all very mysterious. We've got to somehow remove the mystery and remove the black box and make it easy and transparent for them to see what's going on, to know how to partner, to know how to navigate these strange structures called universities.

It is incumbent on universities to remember the global part of "global economy" and "globalization." We cannot do it in isolation and, in fact, I would argue that by focusing on global partnerships and our knowledge-transfer and economic-development activities, we are also helping the companies and partners in our regions and states and beyond to cope better with the effects of globalization. An economic historian at UNC has written a wonderful paper, *Driving Down Highway 52*, in which he talks about leaving the ivory tower and the lovely surrounding of Chapel Hill and riding through one of the most economically depressed parts of the state, seeing textile mills and manufacturing plants shuttered. He figures that if he stopped and talked about how wonderful the global economy is with those people they would probably run him out of town. As we seek to pursue the engagement initiatives that I talked about, we have an obligation to do so also in a global sense and to use that knowledge and those partnerships and that synergy to leverage additional information and assistance to help such companies cope better, to get access to innovation, to retool what they are doing, to understand markets and look beyond the landscapes in which they have traditionally operated.

Partnership is fundamentally important with whoever is working in this space, in state and federal agencies, not-for profit organizations, and educational institutions. Partnering is the key because there is too much to be done and too many resources are required for any university to be effective alone.

A Better World

AUTM is beginning to address this conversation and to position the profession of tech transfer to be more credible and to have more of a voice and more of an impact in this discussion; it's what we call our *Better World Project*. For 20 years, AUTM has published an annual survey that counts all the things we shouldn't count: licenses and patents and revenue, what everyone always wants to know, but which don't speak to public impact. The *Better World Project* is an attempt by AUTM to do just that. The *Better World Report* is a series of twenty-five in-depth stories of university innovation that has been translated into products that have been the bases for starting companies, that somehow changed an economic circumstance, a human-health circumstance, an environmental circumstance, with significant impact regardless of financial implications. A companion piece, *Reports from the Field*, contains a hundred shorter versions in vignette form. The objective is to educate our members and also to educate other interested parties who don't quite understand why universities are involved in this. The stories are contained in a searchable database and more will be added over the next few years from the United States, Canada and around the world. We are sending these reports to all members of Congress and to most of the agencies in Washington that lobby for research dollars and technology-transfer dollars. We are stepping up to this conversation in a major way to try to have a more positive impact on how the conversation about the universities' role in knowledge transfer and economic development is going, and what impact it should have and what should we be looking at in the future.

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Mark Crowell is associate vice chancellor for economic development and technology transfer at the University of North Carolina at Chapel Hill. Prior to joining UNC in 2000, he held similar positions at North Carolina State and Duke Universities. He has extensive experience in technology transfer, new-company development, seed capital formation, economic development, and research park development and marketing.

Dr. Crowell's beyond-campus duties in the Research Triangle Park area of North Carolina include serving on the boards of directors of the North Carolina Biotechnology Center, of the Research Triangle Regional Partnership, and of the Council for Entrepreneurial Development. He is an appointed member of the Orange County (NC) Economic Development Commission, and he recently co-chaired the *Entrepreneurial Companies* working group in conjunction with a North Carolina Governor's Office initiative to develop a *Statewide Strategic Plan for Biotechnology* in North Carolina.

Crowell has extensive national and international speaking, consulting, and management experience in organizations and initiatives related to technology transfer and innovation-based economic development, including the American Academy for the Advancement of Science and the National Academy of Sciences. He is the 2005–2006 president of the Association of University Technology Managers, and is faculty advisor to the Carolina Student Biotechnology Network.

Q&A

Tony Shelton (Cornell University): Can you give an example of one of those stories?

Crowell: I'll give you one from my university. A professor in chemistry, winner of the Presidential Green Chemist Award, has done a lot of work in environmentally friendly manufacturing processes. He has an invention that uses super-critical CO_2 as an environmentally friendly cleaning agent that was first commercialized through Hangars cleaners, which is a franchise dry-cleaning chain that uses this patented process and does not use perchloroethylene. It hasn't been a terribly successful business model, it's not a venture-capital play and it hasn't created lots of jobs. But it is getting an environmentally friendly process out there. Another great example is from East Carolina University, a smaller regional university in our state with a good family-medicine-oriented medical school. Professors in speech pathology developed a novel anti-stuttering device that was featured on the *Today* show. This device is amazing in its ability to reduce stuttering in people for whom nothing else has worked. This invention hasn't generated a lot of money for East Carolina but it has had tremendous impact on the lives of a large number of people.

I encourage you to go to AUTM.net. You can order copies or you can search the database online. It will grow over time and I think it will be a helpful tool for many of you.

Steve Pueppke (Michigan State University): I agree with you that the major criterion of success shouldn't always be dollars, but how do you argue that this isn't the best measure of tech-transfer success?

Crowell: You keep telling stories such as those in the *Better World Report*. And you look at places that are up-and-comers in tech transfer—such as UK universities that are turning out more companies and more products. What are they doing differently? Their tech-transfer offices are funded by the government. The problem with our model is that many of us have set our offices up with the expectation that they become self-supporting, which places us in a vicious cycle. My office gets 20% of what we make. My chancellor says he agrees that it's not about money, but when I ask for more positions for my office he asks what were our revenues last year. So, it's a tough one. I don't have any magic solutions but people are working on it. Stay tuned.

Milt Zaitlin (Cornell University): One of my observations is that tech-transfer offices often don't have the expertise that they need and are not willing to go out and get it.

Crowell: I agree. The level of expertise and agility varies widely as you would imagine. I would not agree that it's true across the board, but it is true in many cases. Many of us—even those who have good understanding of what's patentable and what should be patented—probably have patented more than we should have. Fear that we are going to miss something drives a lot of that. Again, what should the mission statement for your tech-transfer office be? Is it there to generate money and make sure that you don't miss one? Or is it there to enhance the research environment to get knowledge assets out to help people and adopt a philosophy that you only patent when that is the best way to achieve that objective? In the pharmaceutical world you would never not patent something that is fundamentally important, whereas in the IP world it's quite common to find pathways to the market that don't require patents. And as I said earlier, many of us adopted or developed our practices around the pharma model. But we are trying to address these issues. A speaker today said that we've got to stop maintaining patents that didn't go anywhere and that's also very true.

Audience Member: Do you have any idea of how much the technology transfer coming out of universities is going to the state and to companies?

Crowell: I can give you a couple, but they are not great numbers. There haven't been longitudinal studies on that. When I was at NC State we did one of the most entrepreneurial things I've ever seen any university do. We took $10 million out of the university's endowment over 3 years, and created a venture fund. We used that fund to invest in fifteen companies and over a 4-year period those fifteen attracted almost $200 million in follow-on funding, created about 400 jobs and twelve of the fifteen located on NC State's research campus. So, irrespective of the eventual return on investment, the economic development success spoke volumes about the value of this type of activity. Furthermore, we tracked how many of those jobs went to NC State graduates of 5 years or less duration; we were looking at brain drain. So we had some wonderful research going on. The VC people, at the end of the day, want to know what's the financial return and that story is not out yet. It's going to come in soon. The fund was from 1998 to 2000. Some of the companies are starting to cash out, so I hear they are going to actually make some money on it to boot. There's not a lot of good numbers longitudinally. At UNC Chapel Hill we've done thirty-four start-ups in the past 5 years. We have a research budget of almost $600 million a year. I think some of that was pent-up demand, some of it was just a new sort of can-do approach and a new "lets get the deals done and out of here," and a new mandate from me to the staff saying, "I don't care if you leave a dollar on the table—I want you to do a good deal but I'd rather have deals get done then get hung up on squeezing every dollar, every share of stock." Somebody might come in and criticize the economic portion of our deals, but I think they would at least be impressed with the deal-flow.

Audience member: Do offices such as yours administer in terms of whether something will be patented or not? Do you become gatekeepers to what research should be done? If research is not going to be patentable, is advice given to drop it although it may have tremendous potential for public good?

Crowell: We try to make sure that more is discussed than patentability. Our assumption is that anything that is disclosed to our office is patentable. We presume that our faculty are so good at what they do and are so out front in their fields that if they come forward

My university spends $2.5 million a year filing patents.
It's unbelievable how expensive this is.

and say, "I've got this invention I think is patentable," we generally agree that it probably is. The question is: "Should it be patented?" And that's where we try to look at business and market and application and issues of the type you are alluding to, and try to make a decision that has no implications in terms of the quality of the science. We simply look at our patent budget as a venture capitalist would. My university spends $2.5 million a year filing patents. It's unbelievable how expensive this is, and my view is we ought to be just as picky as venture capitalists who turn down at least ten to twenty projects for every one they take. I don't know if that answers your question, but we try not to play that gatekeeper role. We try to make sure that it's at least done objectively and not subjectively. We may find something in the patent literature that kills it and which then sends a company away that otherwise would have funded the research, but that's going to happen anyway. That's good due diligence and good in the long-term for our partners.

Supplementary Presentation

Agricultural Biotechnology and University-Industry Research Relationships: Views of University Scientists and Administrators and Industry[1]

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In 1998 the pharmaceutical/agricultural biotechnology firm Novartis (which has since created the agricultural biotechnology company Syngenta) signed an agreement with the Department of Plant and Microbial Biology of the University of California at Berkeley. Novartis provided $25 million over 5 years to the department to fund research into plant genomics and offered UCB scientists access to Novartis's proprietary technology and molecular databases. In turn, Novartis gained representation on the department's research committee and obtained rights of first refusal to negotiate exclusive licenses for up to a third of discoveries made in the department by faculty members who signed the agreement. The agreement created a controversy on the UCB campus. Some faculty spoke against the agreement while other faculty and many administrators supported it. Press and Washburn (2000) reported that a survey of faculty of the College of Natural Resources found deep divisions over the benefits of the agreement (Busch *et al.*, 2004). An external review of the "Novartis-Berkeley deal" recommended, among other things, that UCB should avoid industry funding arrangements that involve large numbers of faculty with academic units; and to ensure that such deals do not impinge on regulatory relevant research such as risk assessment (see Busch *et al.*, 2004).

[1]This study is part of the project *Public Goods and University-Industry Relationships in Agricultural Biotechnology* funded by the Cooperative States Research, Education, and Extension Service of USDA under IFAFS Agreement 2001-52100-11217. Any opinions, findings, conclusions, or recommendations are those of the authors and do not necessarily reflect the view of the US Department of Agriculture.

One result of the agreement was that civil society groups critical of agricultural biotechnologies have become more focused on the relationship between the biotechnology industry and university scientists' research agendas. This is also a controversial topic on many campuses, especially those of land-grant universities. Land-grant universities have long maintained close ties with various sectors within the agricultural industry, but they are also publicly supported institutions with a mission to serve the public good. A host of scholars debate the ability of a public institution to serve public interests while also serving specific private organizations (Lacy, 2001; Krimsky, 2003; Busch *et al.*, 2004).

Appropriate Links

Three related developments lie at the center of the debates concerning the appropriate links between universities and private firms:

- legislation such as the 1980 Bayh-Dole Act;
- the decrease in state and federal support for agricultural research relative to private sector investment; and
- the increasing emphasis on university biotechnology research as an engine of innovation that will lead to regional and national economic development through the commercialization of technologies by industry from university discoveries (Slaughter and Leslie, 1997; Busch *et al.*, 2004).

Bayh-Dole enables universities to patent the results of federally funded research in order to provide incentives, through royalties, for universities to link with industry to commercialize technologies and scientific knowledge. Meanwhile, as public money for agricultural research declines, private-sector firms become more attractive to university scientists and administrators as sources of operating funds, research facilities and proprietary knowledge and technology. And with the protection of patents and the potential for licenses, including exclusive licenses, university-based science becomes more commercially attractive to firms. These changes are couched within an evolving view of universities as critical centers of knowledge and talent that can generate economic growth if the right public policy and institutional capacities are in place (Etzkowitz, 2001). In many cases, remaining public funds—especially state funds—are contingent on university scientists identifying industry partners and a potential economic development outcome, such as increases in jobs through the creation of private companies "spun-off" from university research efforts.

Regarding university-agricultural biotechnology industry relations, these types of changes have resulted not only in increased scrutiny of university-industry relationships (UIRs) by civil society organizations and the scientific and popular press (*e.g.*, Press and Washburn, 2000; Nature, 2001), but also in shifts in rewards structures and scientific cultures within academic departments. University scientists are more often evaluated according to private-sector criteria, such as developing a self-sustaining or profitable laboratory through patent activity, licensing revenues and external funding (Kleinman and Vallas, 2001; Kleinman, 2003).

Analytical Frameworks

Researchers who analyze UIRs often examine the broader institutional consequences of the relationships. They assume that the industry and the university play overlapping but different roles in society, and question whether those roles might be compromised when the individuals from these two organizations increase their interaction in particular ways. For example, Hackett (2001) found that society increasingly sends an ambivalent message to universities. That is, universities should perform their traditional (less business-oriented) role while also responding to national economic imperatives.

In this vein, Slaughter and Rhoades (1996; 2004) and Slaughter and Leslie (1997) provided an informative framework for understanding the changing societal role of universities. They argued that we are witnessing the emergence of an "academic capitalism." Academic capitalism refers to the role universities have adopted as the knowledge economy has emerged over the past three decades. The knowledge economy refers to the set of intellectual property policies and practices that convert advanced knowledge into the raw material for commercialized products and services. Because much of the advanced knowledge in the United States is contained in research universities, a central component of the construction of the knowledge economy has been to integrate the research university into the intellectual property process [see also Kenney (1986) and Busch *et al.* (1991)]. Global economic restructuring, whereby states find it increasingly difficult to raise revenue from mobile firms, drives this change. In addition, the end of the Cold War removed the dominant rationale for state funding of universities and state sponsoring of university-industry links: national defense. These authors document a bipartisan political shift toward a "competitiveness agenda" and away from a Cold War or defense agenda. The competitiveness agenda entails the focus on universities as engines of innovation and potential growth, and an emphasis on competitive grants for allocating federal funds [see also Croissant and Restivo (2001)].

In addition, Slaughter and Leslie (1997) asserted that, as a professional class, academics have shielded themselves from the vagaries of labor markets by maintaining a monopoly control over specific kinds of knowledge in exchange for a tacit social contract: do research to benefit society, not to maximize private gain. However the policy changes to overcome the economic crises of the 1970s and 1980s have led universities and professors to adopt market-like behavior, using goods, services and labor to pursue profit. Slaughter (1990) has also noticed the rise of a new "institutional class" comprised of university presidents and industry CEOs. They claim they need unlimited authority and resources to produce this common good. They define that common good as funding universities to promote entrepreneurialism among faculty and the commercialization of scientific knowledge to inspire economic growth [see also Croissant and Restive (2001), Etkowtiz (2001), Slaughter and Leslie (2001), Krimsky (2003) and Busch *et al.* (2004)].

Owen-Smith and Powell (2001) found that some scientists tended toward an "old school" orientation, skeptical of increasing ties between universities and private-sector firms. Other university scientists embraced the blurring of traditional lines between the university and the for-profit sector. And still other scientists fell somewhere in the middle between the two extremes. That is, some "old schoolers" felt compelled to move into commercial science in order to develop a research program and to retain cutting-edge faculty. Meanwhile some entrepreneurs recognized that the breakthroughs generated from new arrangements threaten important aspects of the university.

Data and Methods

We are building on this study, and others, by developing and analyzing three complementary databases:

- in-depth interviews with eighty-four scientists and sixty-six research administrators at five major land-grant universities (LGUs), supplemented by interviews from two private universities, a small LGU, and one public non-LGU;
- interviews with sixty-three scientists and managers at thirty agricultural biotechnology companies; and
- a national survey of academic bioscientists.

The interviews generated qualitative information regarding the motivations, constraints, advantages, and limitations of UIRs. Insights from the case studies informed our behavioral model and the design and enumeration of the national survey as well as fostered our understanding of the survey results.

Our national survey is the first random sample of US academic scientists conducting research with implications for biotechnologies in agriculture, forestry, and aquaculture.

Our national survey is the first random sample of US academic scientists conducting research with implications for biotechnologies in agriculture, forestry, and aquaculture. A response rate of approximately 60% (859 of 1441) was achieved. Contrasting the respondents who received industry support with those who did not, permitted inference about UIR effects on academic research programs. Econometric methods were used to estimate the marginal effects of industry support while controlling for such other influences as the scientists' human capital, research field, and views about the proper role of public science.

Results

Turning to the interview data, we found that university scientists seek out industry partners to access a number of important resources. These include:

- Funding
- Equipment
- Knowledge

- Materials
- Expertise
- Access to databases
- Technology
- Opportunities to place graduate students
- Institutional legitimacy

In their turn, industry personnel establish working relationships with universities to gain access to the following items:

- University scientists
- Graduate students/future employees
- Increased credibility/legitimacy
- Enhanced regulatory success
- Strengthening marketing possibilities
- Leveraging resources and structural linkages (extension)
- Increased research efficiency
- Lower infrastructure costs
- Decreased labor costs

In addition, we asked university scientists and administrators, as well as industry partners, to rate the perceived advantages and disadvantages of UIRs. All three groups were complimentary of UIRs. However, administrators were the most optimistic group, industry second and university scientists were the least positive. In general, industry viewed UIRs as vehicles for:

- Leveraging research money
- Taking advantage of a natural division of labor: basic/applied research
- Facilitating regulatory approval of new technologies.

The most insistent concern on the part of industry was that the division of labor between public/private sector is fading. For example, one industry informant argued:

> What we typically find though is that basic research, less and less of it is being done, and we find we're competing against university labs for the same technologies, *so it's like funding your competitor*. And Bayh-Dole has caused some changes in the way that universities protect IP, and some of them are very, very aggressive, so you've got to be careful (emphasis added).

Administrators viewed university-industry relationships (UIRs) as essential, bringing with them a number of advantages.

Administrators viewed UIRs as essential, bringing with them a number of advantages. These include:

- Accelerating product development which leads to economic growth
- Leveraging additional scientists through wider networks
- Provision of additional research funds

And administrators saw a focus on biotechnology and ties with industry as partially driven by public policy and state funding of the land-grant system:

> Another thing that helps is…for example,…the fact that the state recognizes biotechnology as an important component of their economic growth also helps identify biotechnology as a university priority area because it meshes well with the state vision for itself.…We always use leveraging as part of our case to the state…

The main concern raised by administrators was that UIRs could create haves and have-nots among their faculty, leading to problems with morale and collegiality. For example, one administrator argued that:

> . . . in some instances you run the risk of faculty becoming too jaded by the money that industry might throw at them, by the prestige they might get by working in the industry . . .

While university scientists were the least favorably disposed toward UIRs, they tended to see more positives than negatives.

While university scientists were the least favorably disposed toward UIRs, they tended to see more positives than negatives. Positives included:

- Leveraging research money
- Wider scientist network
- Financial support for graduate students and post-docs

But scientists also had concerns about communication and publication restrictions and the manner in which universities often handle IP issues:

> …there may be more constraints than what a university scientist is used to; we're used to open access, discussing your research results at meetings, publishing, talking with others about it...[depending on the research] a company can tell you, No, you can't go to this meeting, you can't disclose any of this information.…
>
> The university wants to patent, big time. It has almost become more important…than publications. …it's status for the university… I think more and more universities are being judged on how many patents they [produce].

Turning to the survey of university bioscientists, our intent was to address one central question and two guiding questions.

- Central question—Does industry support lead to more applied and excludable research, diminishing basic and publicly accessible knowledge about ag biotechnology?
- Guiding questions—What factors affect the "basicness" of scientists' research and the "excludability" of their discoveries?

We measured "basicness" by having the scientists estimate the percentage of their research identified as basic (*vs* applied). We measured "excludability" by having the scientists estimate the percentage of discoveries that may be withheld from public use through proprietary tools and strategies such as patenting.

Basicness

Using National Science Foundation (NSF) funding as a base, sources that led to more applied research were, in order:

- Industry
- State
- USDA
- Other federal and miscellaneous
- Non-profit foundation

In addition, important factors that influenced the basicness of scientists' research agendas were the values of the scientists themselves. In general, the more importance a scientist attributed to making theoretical contributions as part of his or her research program, the more basic the scientist's research. Also, if a scientist develops a research agenda in part for its potential to publish scholarly articles the research agenda is more basic. Contrariwise, if a scientist thinks it important to patent research results, the research program tends to be more applied.

Excludability

Again, using NSF funding as a base, sources that led to more excludable research were, in order of importance:

- Industry
- NIH
- State

Scientists' values continued to be important determinants of the profile of scientists' research programs. Regarding excludability, the more importance scientists attributed to providing nonexcludable benefits through their research, the less excludable the program. Also, if scientists believed that it was important to make significant theoretical contributions, their research program was less excludable or proprietary in nature. And if scientists believed that it was important to patent discoveries, their research programs had a more proprietary or excludable character to them.

Conclusions

In general, industry funding brings modestly less basic and more excludable (*e.g.* patentable) research than does NSF or NIH funding. Industry is wary of the decline in the level of basic research at universities, but contributes to this decline through its funding relationships. This finding points to the importance to a number of parties of continuing to publicly fund basic research at universities. This argument also holds true for public-versus-private biotech research. Industry funding tends to lead to more excludable or proprietary agendas as designated by the scientists themselves. To generate a broad array of biotech interventions, *e.g.* minor and major crops and traits (Welsh and Glenna, 2006), diverse sources of support appear to be important.

Professional values exert stronger effects on research basicness and accessibility than do funding sources.

In addition, professional values exert stronger effects on research basicness and accessibility than do funding sources. This final finding points to the importance of "selection" of academic scientists by schools and departments in order to maintain a distinction from the private sector and to provide balance in the research portfolios of university scientists.

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Rick Welsh joined the faculty of Clarkson University in 2000 as an assistant professor of sociology. Promoted to associate professor in 2004, his research focuses on economic and social change and development with emphases on agriculture and food systems, the sociology of science and technology, environmental sociology, and social movements and collective action. Prior to Clarkson, he served as a program officer for the Henry A. Wallace Center for Agricultural and Environmental Policy at Winrock International Institute for Agricultural Development, and as interim associate director and policy analyst for the Henry A. Wallace Institute for Alternative Agriculture in Greenbelt, MD, and as director of the US Department of Agriculture's Southern Region Sustainable Agriculture Research and Education Program.

Currently, Dr. Welsh serves as associate editor and book-review editor for *Renewable Agriculture and Food Systems* and as a publication advisor for *Agriculture and Human Values*. He is a member of the Agriculture, Food and Human Values Society, the American Sociological Association, and the Rural Sociological Society.

He received his doctoral degree in rural sociology in 1995 from Cornell University, and a master's degree in food and resource economics from the University of Florida, Gainesville.

Q&A

Audience member: What is the status of the survey?

Welsh: We've finished collecting the data and are starting to publish the results. We have publications coming out in *Sociological Quarterly* and *Social Studies of Science*. We were unsuccessful at *Science*, but are having some success getting it out elsewhere. We are just scratching the surface in terms of analyzing the data.

Steve Slack (Ohio State University): Please make a point of drawing NABC's attention to the resulting publications.

Welsh: I'll put you on the list. Our grant rationale included outreach and education, which is one reason I am here. I'll definitely get those to you.

Bruce McPheron (Pennsylvania State University): This is an observation rather than a question. Several of us attending this meeting are experiment station directors in the land-grant system and tomorrow our 5-year plan of work is due. It's a new system that USDA has developed to allow us to build our plans to direct our experiment station expenditures from 2007. Under that system, they built in sections under each of the programs that we propose, to list what we assume will be the outputs and outcomes of that federally funded research and extension. And they put in only one metric: number of patents. So, what's the message that coming to the administrators of these organizations? They couldn't think of anything else across the system that they wanted to ask us about in advance, only how many patents will come out of each of these programs.

Welsh: That helps explain and adds some substance to our findings—what is considered most important.

PART IV

PANEL DISCUSSION

Panel Discussion

MODERATOR: STEVEN A. SLACK
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Steve Slack: The panel members will provide brief self-introductions to provide context in terms of their responsibilities in the system; each has or has had important roles in land-grant institutions. Then they will share some thoughts emerging from Rick Welsh's presentation in particular and the meeting in general, and I will then ask Rick to join the panel for questions from the audience.

Steve Pueppke: I'm a research administrator at Michigan State University as of a couple of months ago, having spent 8 years at the University of Illinois doing the same thing at the ag experiment station.

Part of my job has been in building research relationships with companies. In my experience, this generally plays out as somebody like me contacts somebody with a similar position in a company, saying, "Your people and our people ought to get together to discuss common interests." Behind this—if you are a university person—is the vision of obtaining funding, which is a powerful driver. At the university, we make a few phone calls and ask people to think about projects of possible interest to our industrial friends. We get on a bus or a plane and get together and have an interesting, thought-provoking half-day discussion—throwing out ideas that we think might interest our friends in industry—and return home. And we get busy. And at some point we realize, "Gee, haven't seen any checks." We call up the colleague who says, "They were really interesting ideas, but we are not really sure that we're ready to fund them. But we are genuinely interested in the interaction, so why don't we get together again?" With one company, we went through this cycle five times. Eventually, my industrial colleague obtained a new job and I had to make a new connection. Then I got a new job!

What is a nice standard for building relationships with companies that are not driven primarily on the notion of a money flow?

As an administrator, one does need to manage expectations in building relationships that go though administrative channels. It's different from building on scientists who have common interests. Sometimes I think that we administrators would serve ourselves well by listening more to the faculty and coming in behind them more.

At Michigan State, when I contacted my first company—actually they contacted me—to start this process, at the end of the conversation the gentleman asked, "Michigan State, what do you want out of this? How do you want to proceed?" I responded: "I don't want to talk about money, and we don't want any money from you. At least, not now." And he said, "Thanks. Let's proceed and try to build a relationship." I have thought a lot about what is a nice standard—at least for us administrators—for building relationships with companies that are not driven primarily on the notion of a money flow. There's a lot that we administrators don't know, a lot of commonality that can be found, things that can emerge from conversations. Sometimes such things emerge and are shared more readily when no money, project or proposal is on the table.

Molly Jahn: I've been a plant breeder at Cornell for 15 years and, as of August 1, 2006, I will move to the University of Wisconsin College of Agriculture as dean. I have participated in relationships with industry for a number of years. I have also been the object of study in this regard: social scientists—sociologists and economists—have evaluated the impact of our work.

University scientists have not lost any ambition to have impact. Idealism is alive and well. However, I agree with a point Paul Thompson made: many university scientists, including those with strong desire for relevance and impact, are woefully, even shockingly, ignorant of how that actually happens, despite the best efforts of administrators and technology-transfer offices and, sometimes, of our commercial partners. Something I have thought a lot about is the extent to which some of the traditional functional divisions—those legs on a stool—can actively obscure potentially beneficial connections. Some of the success that my program has had results from my not knowing about the legs of the stool, as someone who came to Cornell from outside the land-grant system. I did my own extension. Also, at Cornell we have the benefit of strong relationships with companies from the era when things were freely distributed, when packets of seeds went out the door without a backwards glance. My career spans the transition; now for everything that leaves—even in a project with organic farmers—material transfer agreements (MTAs) have to be signed.

Successful relationships that generate value for both sides generate money for the public sector.

Again, it's important to realize the degree to which desiring to have impact is different from knowing how to achieve it. Some do know how to achieve it and making connections with them is important. Also, as a university scientist I would argue that my ability to contribute to economic and workforce development—both of which are difficult to measure—is affected by our credibility as a public institution and the perception that we offer objectivity. One of the things that the institutions I work for think a lot about is not *avoiding* conflict of interest, but acknowledging that engagement generates conflict of interest and conflicts of commitment, and that, as institutions, our job is to manage them as opposed to avoiding them. There are many ways in which this is done, one important way in which we can contribute to this—and this is something we have experimented with in my research program for the past decade—is, as public-sector scientists engaged heavily with multiple facets of the private sector, we declare our principles ahead of time. And, as public-sector scientists—and this speaks to a point that Rick Welsh made about public-sector activity being, in some respects, fundamentally different from proprietary activity—our principles are different from those that guide proprietary activity. We are not fundamentally a profit-making enterprise, and I have never made decisions—either individually or on behalf of my institution—based on the financial aspect of a relationship. However, in my experience, successful relationships that generate value for both sides generate money for the public sector. We just passed the $100,000 mark in gifts to a consortium I am part of; each year we are offered royalties—considered "research assessments," resulting from less-formal relationships—of at least $50,000, which is very helpful to a public-sector research program, although our fundamental motivation is impact and distribution of benefit as opposed to profit. As economic and workforce development are hard to measure, so are objectivity and credibility. Patents are a poor indicator of impact. Licences are better, but still present issues. Evidence of engagement is less difficult to at least describe.

In an era of declining public-sector support for all types of research, I concur with Rick Welsh that we are in a stronger position with respect to credibility and objectivity if we are working from diverse funding portfolios, which has been a feature of how we have done business, allowing us the independence to declare some of those principles as we intersect with sources of funds.

Milt Zaitlin: I am a professor emeritus of plant pathology at Cornell. I was once the director of Cornell's biotechnology program and I co-teach a class in plant biotechnology.

I want to deal with an aspect that has emerged from the meeting: I am concerned about the poor climate for the introduction of genetically engineered crops, particularly in the food arena, whether from the public or private sector.

I don't need to tell this audience that genetically engineered foods have been demonized by a number of interest groups, and the public remains sceptical, as shown by surveys. In particular in Europe, but also in this country, when asked, most people are opposed to it. They don't know a lot about it, but have been told that it's bad. I was struck by what Richard Broglie said about the new oils that DuPont has in the pipeline. What will the opponents do when these come onto the market? There have been objections to canola oil and cotton fibers from genetically engineered plants, even though they contain no genetically engineered component. They are said to contain an "essence" of genetically engineering, which is troublesome.

My area is plant virology, and towards the end of my career we developed a technology for making virus-resistant plants by transformation with the viral replicase gene. Cornell patented this technology and licensed it to Monsanto, which had established a potato company in Idaho, NatureMark, where they were bulking up to produce Russet Burbank potatoes resistant to the Colorado potato beetle (via *Bt*) and to the potato leaf roll virus (via the replicase gene). Lo and behold, the fast-food industry—the principal market for Russet Burbank—refused them because of fear of being picketed. The NatureMark operation closed down despite the fact that it was a good product that would have benefited the farmers who were embracing the technology.

It's distressing that a number of excellent technologies in the pipeline may not see commercialization.

It's distressing that a number of excellent technologies in the pipeline may not see commercialization. My expertise relates to disease resistance and many virus resistances have great potential utility, yet companies, at least in this country, are unwilling to commit to this approach because of these objections and costs of the regulatory process. We can only hope that things will change in the near future. They cannot cry wolf forever. Warnings of how dangerous these products are will eventually be tempered by the fact that consumers are not getting sick.

Slack: The forum is open to general discussion.

Audience member: GM technology is not transparent enough. Some consumer concerns may be valid. Is there an institution where the pros and cons could be set out clearly, for particular use by policymakers?

Rick Welsh (Clarkson University): A large part of the public perspective on agbiotech has been driven by lack of comfort with certain agrichemical companies that have dominated the market. If a broader diversity of firms were involved, it would be harder to mount campaigns and they would be less successful. There is movement to provide greater transparency, which may have a profound effect.

Jahn: Many of us at universities have failed to understand the extent to which we think we are doing God's work, whereas the public sees us as corporate tools. We fail to recognize, often, the extent to which many issues—particularly the corporate control of food—are confounded. We want to have a conversation about safety, which is the essence of the discussion, but the picture is more complicated and we are unprepared to disentangle the issues, and neither is our counterpart. So, we have the same conversations year after year. I didn't understand the extent to which this college—Cornell—was perceived that way until I began working with the "organic" community. To balance that, we ended up with some products that that community wanted, so we developed dialogue and at one point the only thing I had to offer was a transgenic product. I asked them how they would feel about it—a silencing technology, not "frankenfood"—and they answered, "I don't know." I considered this a significant victory, because it finally presented the opportunity to discuss the product rather than who is running the supermarket, *etc.*

Slack: Milt, you mentioned being in charge of the biotech program here at Cornell. When that was set up there was funding from the state, with certain expectations about economic development tied in. Largely it was operated as a grants program that, in part, matched up with industry. So, you had a mix of public and private funds. How did the blending of funding sources affect the nature of research that was done?

Zaitlin: We let the faculty decide what they want to do. We never told anyone, "Work on this project and you'll get money." The program has changed. The money for economic development comes from New York State with the objective of fostering development of small businesses. So, the program has actually supported research faculty by giving them some of that money. The way it works now, matching funds are provided to faculty members who go out and get outside money.

Slack: Has that changed the dynamic of the kinds of research done?

Zaitlin: Oh, yes. When we started, we funded a lot of basic research, whereas now we fund essentially none. It's driven by the ability to attract matching industry funds.

Tony Shelton (Cornell University): Milt, when you were running the biotech program, how many businesses were spun off from those relationships, and how many continue?

Zaitlin: I haven't been associated with the program for a couple of years, but they claim that they have generated thirty spin-offs. And a few have done fairly well.

Allan Eaglesham (National Agricultural Biotechnology Council): Molly, although your progress with the people in the organic-farming community was modest, do you see opportunities for meaningful dialogue at some point in the future and what can we do on our side of the fence to foster that?

Jahn: I see many opportunities. I agree with Milt that the argument that you will grow a second head can last only for so long, especially given the predominance of foods that contain the "essence" of genetic engineering. One of the issues has been the nature of the first, perhaps also the second, generation of genetically engineered traits being offered, which continue to confound in terms of corporate control of food versus safety of the technology. I have tried to listen carefully for that mixture and to take it apart, not to disregard the emotion over the structure of our food supply, but to separate that from the conversation that we are, in theory, really having. As we worked with that community, we established credibility, and we are now a resource that that community looks to. We were not similarly viewed even 5 years ago—and I believe we are rare among public-sector scientists. That is the basis for the conversation. If there were more engagement of the public sector with that community there would be commensurately more opportunity for meaningful exchanges, which do not develop from adversarial stances. Modest, yes, but a significant victory for me in that it was a genuine interaction focussed on communication over a real question—not us peddling a product that they didn't want—a real question that the community had and potential technical solutions. And that is really what the public sector was introduced to do about 150 years ago.

Welsh: Molly, you worked with them over time and they trusted you. They trusted your perspective on an issue they knew that you know more about than they did. That's the way it works. They will listen to that from you but not from someone else. You had proven yourself, in a way. Can that be extrapolated, somehow?—that is the question.

That relationship started out with us listening and asking, as opposed to showing up and telling and selling.

Jahn: Let me emphasize that that relationship started out with us listening and asking, as opposed to showing up and telling and selling.

Bruce McPheron (Pennsylvania State University): I have a question for Rick, but first I'll follow up on that last exchange. I talk to many extension audiences and stakeholder audiences, and I try to tell them that the thing that differentiates the land-grant system from a Google search is that we have done the filtering of the results. When we give advice, it's science-based and we hold our credibility very dear. Molly, that may be one of the values that you would put at the forefront.

Rick, do I recall correctly that one of your outcome slides from discussions with the industry people in the survey was a perception that we are doing less basic research?

Welsh: Yes, essentially echoing what Milt just said, that industry funding tends to be linked to the availability of public funds. We found that industry funding tended to draw research programs toward more-applied outcomes, and even though industry was part of that dynamic, they felt it had either gone too far or wasn't a positive outcome because basicness was what they thought universities should be focussing on. They argued that there was a comparative advantage there because of the public-sector nature of the university. Also it's not the university's role to compete with industry, and they felt that they were in competition, which is not what they wanted.

McPheron: That's an interesting perspective. I would say that the flip-side is that the ag-production stakeholders with whom we interact—and, in fact many of the more vocal members of our college—would argue just the opposite, that all we do is basic research. So, there's an interesting perception that's based upon your starting point, that I think we need to be aware of, at least, as we plan our research agendas.

Ralph Hardy (National Agricultural Biotechnology Council): In the twentieth century, agricultural research was marvellously successful in terms of food productivity and associated aspects. In the twenty-first century, agriculture—probably better than any other single entity out there—has the potential to address an array of societal problems. How do you see we are going to communicate that potential, and structure and fund it to make it a reality?

Slack: That sounds like a "dean" question. Molly?

Jahn: I would argue that we will communicate more effectively if we have the qualities that I highlighted: maintenance of credibility and objectivity as already perceived by many in the public. On the other hand, many in the public don't perceive that, and to the extent that those dynamics are in play, we don't communicate effectively. GMOs provide the classic illustration: we've been out there answering questions for decades and are still unable to deliver the technology. On my mind is the extent to which public institutions are becoming an extension of capitalism, then there is nothing to distinguish us from the private sector. Also, as administrators, we need to watch out for the perception that our scientists are engaged in conflicts of interest, with resultant loss of credibility.

With regard to big-picture issues—energy, global warming, economic viability of rural communities—the capacities of the land-grant colleges are perfectly crafted to address them, albeit possibly with new approaches.

With regard to big-picture issues—energy, global warming, economic viability of rural communities—I would argue that the capacities of the land-grant colleges are perfectly crafted to address them, albeit possibly with new approaches. Frequently we perceive competition when, in fact—particularly with declining resources—we should be thinking about partnerships, university-industry being an important one. We've had great success partnering with non-profit organizations, which was an important vehicle into the "organic" community in the absence of an extension apparatus. But we had a message and we knew that we needed to learn. Our ability to react to current and future problems will depend on the extent to which we can craft common-sense, comprehensive approaches as opposed to, "Here is research, here's teaching and here's extension."

Pueppke: We've made progress already. In my academic career I've seen movement away from heavy emphasis on production agriculture. We haven't turned our back on any of that, but we've moved on and expanded our view and captured the food system in our thoughts, and we've become good at obtaining funding and building relationships with a variety of funding agencies. I see it as a logical extension of this. We have to keep on that pathway.

Jahn: I didn't touch on funding. The federal agencies are important. Madison and Cornell rely heavily on NIH and USAID through USDA. State money is also important as are industry relationships of many sorts. Other avenues of public support exist; our non-profit relationship has been a phenomenal advantage for us in terms of connecting with a community with whom we could not otherwise have communicated.

Slack: Rick, it's clear that your research touches on a very important dialogue and that there are strong feelings on it in our leadership. We look forward to your information as you release it, and further interesting discussions in due course.

PART V

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