
NABC7: An Overview

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After a day and a half of discussion and debate on the issues of gene discovery, of gene ownership and access to genes, the recommendations of the 40 participants at the 7th annual National Agricultural Biotechnology Council meeting centered on a few critical issues. Those included ensuring the survival of long-term basic research and inserting social responsibility into the agenda-setting process to facilitate discoveries and their development and commercialization to ultimately benefit the public.

At each of the previous annual meetings, organizers strove to get participants thinking about the issues from all perspectives and to ultimately formulate recommendations they can then share with policymakers. This year's meeting, held on the campus of the University of Missouri-Columbia, certainly succeeded in achieving its goals. Workshop members and plenary speakers from a variety of backgrounds offered suggestions that reflected their concerns and goals on the issues of competing rights, the role of governments and public institutions, and research policy related to gene discovery, ownership and access.

The timing of the meeting was especially appropriate because agricultural biotechnology is advancing at such a rapid rate that obtaining answers to questions about gene ownership and access have become critically important. The major agenda item was the discussion of policies about intellectual property rights (IPR) that control the transfer of knowledge in the molecular biology of agricultural commodities to new technology for users. These policies generally establish the ownership rights to intellectual property, the obligation to disclose inventions and conditions of access, the rights of research sponsors to intellectual property resulting from funded research, and the rights from informal innovation by farmers.

As one can imagine, the viewpoints set forth were as varied as the 12 speakers and the conference participants who represented consumer groups, industry, government and academia. For example, Wisconsin family farmer, John Kinsman, who is also President of the National Family Farm Defenders and the Wisconsin Family Farm Defense Fund, focused on the rights of farmers who feel a strong need for self determination, while Ronald Sederoff, Professor of Forestry and Director of the Forest Biotechnology Group at North Carolina State University, voiced his concern about gene ownership restricting access for research. Representing one view of industry, Jack Tribble, Patent Council for Merck & Co., Inc., explained there is a need for cooperation among industry and university researchers so that each can achieve its goals and objectives.

Speaking about defining and ascribing ownership to genes and farmers' rights, Jose Solleiro, Senior Researcher in the Centre for Technological Innovation of the National University of Mexico, asked "how do you put a value on generations of background knowledge that is being tapped for agricultural biotechnology?" In his opinion, more consideration needs to be given to the informal innovation of indigenous peoples, both nationally and internationally.

The speakers echoed essentially the same concerns, namely the effects IPRs have on public and private research efforts and ultimately the production and delivery of products which are essential if society is to benefit from the public and private investment.

"... the heart of the research enterprise is being constrained by the protection of intellectual property owned by others," Sederoff said. It is his opinion that "Constraints on the research enterprise have significant implications for the well-being of society. When researchers are restricted in attempts to extend our knowledge of the world around us, society pays a cost of lost innovation, which is crucial for economic development and the well-being of our citizens."

Concurring was Kathleen Merrigan, senior analyst with the Henry A. Wallace Institute for Alternative Agriculture, who stressed that: patents influence the university research agenda, overly broad patents stifle research, and patents lead to increased research costs. She explained that the current IPR system does not meet today's needs and suggested that a radically different system is needed.

Yet Leanna Lamola, Attorney, sees IPR as helping to maintain the identity and profitability of value-added proprietary factors of identity-preserved varieties. Production contracts are the main mechanism by which producers will participate in identity-preserved systems, she said, adding that risk management is the primary advantage of contract production for both the producer and the contractor. By controlling the timing, quantity, quality and specifications of production, economic efficiencies can be realized. However, production contracts can also present new risks, such as an inability to learn the true market value of products. Producers may increase returns in identity-preserved

systems by moving into downstream activities such as processing. Likewise, producers may decide to fund the development of identity-preserved varieties through research agreements or other strategic alliances with private or public organizations.

In addition, participants identified several critical areas of IPR that need further consideration: partnerships, valuation, proportionality and compensation. Kinsman and Solleiro both talked about proportionality: How do you put a proportional value on knowledge? Participants also agreed that IPR should be examined in relation to the public good, and policies may need to be established regarding access to proprietary information in agricultural technology. Also, public access is needed to provide researchers with genes and tools to facilitate their use; a need exists to reassess the research exemption; and freedom of inquiry is required to preserve the research capability. Merrigan challenged the participants to come up with some action items, not just a set of passive recommendations.

Indeed, the recommendations from the workshops were action-oriented and specific, centering on concerns about the future of basic research and social responsibility in the agenda-setting process. It was felt by participants that policies should balance the social good versus private gain; ownership of genes can have a negative impact on research and skew the research agenda; and patents should have the appropriate breadth. In the U.S., the standards of patentability (novelty, utility and non-obviousness) should be strictly applied in agricultural biotechnology. In addition, IPR should be examined in relation to the public good and equity should be negotiated. With reference to the access to proprietary information in agricultural technology, new principles may need to be established. A need exists to reassess the research exemption. Freedom of inquiry is required to preserve the research capability. One important immediate concern is to deal with policy issues at the interface between ownership and access. The future of agricultural biotechnology requires aggressive discovery and equitable access. Then how is the balance achieved at the conjunction of ownership and access? When is access to be benefited at the cost of ownership and vice versa?

Specific recommendations developed in the workshops can be found on pages 13 to 17. The full workshop reports begin on page 29.

In line with the charge given by Merrigan at the first evening session, the following action items have been gleaned from the synthesis of the meeting activities:

1. Clarify the research exemption for use by public research institutions. For example, clarify this exemption to enable gene sequence information and proven information from all areas to be available for research. The need is to preserve freedom of inquiry and investigation and curiosity-driven research in public institutions, even knowing that these institutions also engage in technology transfer.

2. Establish policy in agricultural biotechnology that fosters legitimate germplasm exchange mechanisms to ensure the fairness of future transactions for the public good.
3. Foster cooperation among stakeholders in agricultural biotechnology. Partnerships are important, but they should be set up in such a way as to not violate the mission and direction of research at public institutions. New partnerships should be forged, but not at the expense of long-term research. The concept of mutual responsibilities among universities, industry and government to maintain vision and mission provides a useful framework for action.
4. Address the conflict between social good and private gain with reference to gene ownership. The main concern is the possible negative impact of ownership on universities or, more broadly, on the research enterprise.
5. Be open to other IPR systems that might be more appropriate for other countries, and decide what kinds of agreements and partnerships are needed with the U.S. IPR system.
6. Consider what is the appropriate breadth of patent claims. This will mean looking at public-private interfaces and the various roles of different institutions.
7. Endeavor to create conditions to facilitate access to genetic resources through mutually agreed upon terms, informed consent, and sharing of benefits in a way that is clear up front. This would include working to empower third world farmers and indigenous peoples and countries to recapture some equitable compensation for their genetic material.

Clearly, each interest group must be actively involved in the development and promotion of new agricultural products. This is especially important for the general public who may not have the background and details to make informed decisions. As Richard Flavell of the John Innes Centre, Norwich, UK, advised, "The consumer acceptance of transgenic crops is not straightforward, and a major public educational effort is needed." And according to Merrigan, there are several ways to help the public become more involved with the research going on at universities, in government agencies, and even within industry.

It was that agreement and understanding that prevailed . . . cooperation among all interest groups, and the recognition and understanding that not everyone will come to the decision-making table with the same background or perspective.

Plenary Session highlights

NABC 7 was organized around three plenary sessions: *Gene Mapping and the Political Economy of Agricultural Research*; *Ownership: Economic, Legal and Institutional Issues*; and *Access: Public and Private*. Speakers at these sessions provided a common core of information for workshop debates and hallway dialogue.

Gene Mapping and the Political Economy of Agricultural Research

In the first plenary session the two keynote speakers dealt with the status of gene mapping and its implications for gene discovery.

Richard B. Flavell, John Innes Centre

Flavell discussed genes and gene mapping for agriculture. He pointed out that new combinations of genes in plants are one of the most valuable resources for future civilizations because they are sources of better food, feed and fiber; economic growth; potential stability; human health and a sustainable environment. Molecular biology is removing the constraints of classical breeding by detecting the presence of genes by their chemistry, and uncovering genetic variation. With the use of computers to determine the sequence and function of genes, the pace of gene mapping on chromosomes has increased rapidly. For example, 10,000 to 15,000 of the 25,000 genes of rice have been identified. In 10 years all the rice genes should be identified along with their chromosomal location. Genetic information from bacteria to humans is being pooled and the field of molecular biology is being unified. Information of great value for animal gene sequence and function will come from the human genome project.

The consequences of this international effort in agricultural biotechnology are many: genetic determination of key traits will become known at the molecular level; geneticists working on related crops will use each other's information much more than they do now; plant breeding will be increasingly automated and selections will be performed by computer without growing plants; new genetic variation in defined genes will be produced at will; and increasingly crops will be modified to serve new customers, markets and industries. Plant improvement programs will be accelerated. There will be increased patenting of genes, and transgenic crops will require the adherence to specific legislation that needs to be harmonized globally. A major concern is that the patenting of genes will inhibit the free global flow of germplasm for use in other breeding programs. The consumer acceptance of transgenic crops is not straightforward, and a major public educational effort is needed. Flavell's paper begins on page 51.

Kathleen A. Merrigan, Henry A. Wallace Institute for Alternative Agriculture
Merrigan spoke persuasively about unresolved problem areas of gene discovery and agricultural biotechnology. She pointed out that the public is now not engaged with the issues of agricultural biotechnology, yet their buy-in is critical. Current 1PR policies of broad patents have a negative impact on research in agricultural biotechnology, including conflict of interest issues and increased transactional costs. Regulatory gaps do persist. For example, currently only voluntary action is needed to prevent and/or delay the onset of public opposition to plants genetically engineered to contain pest or disease resistance factors. She offered several ways for the public to become more involved in biotechnology policy, including having lay people involved in decision-making at universities, seeking the opinions of leaders in the community, and having all undergraduates take a citizenship course that covers biotechnology. Merrigan's paper can be found beginning on page 61.

Gene Ownership : Economic , Legal and Institutional Issues

The second plenary session presented four different viewpoints on the economic, legal and institutional issues surrounding gene ownership.

Ronald Sederoff, North Carolina State University

Sederoff spoke about gene mapping of forest trees, specifically the loblolly pine. He was particularly concerned about gene ownership restricting access for research. A key enzyme for molecular biology in forest biotechnology (Taq polymerase) has been patented by The Perkin-Elmer Corporation. This has essentially made the enzyme unavailable to researchers because of its high cost, and provides an example of how public research is restricted through patenting. At the same time, there is increased pressure on university scientists to work on short-term projects at the sacrifice of longer term fundamental research, thereby eroding our intellectual capital. Research being done at public institutions is affected by the patent process and the funding by private companies.

To foster long-term basic research in biotechnology, Sederoff advocated a research exemption from patents for public research. Many scientists have the false perception that there is a general exemption for university or government-based research if it is purely philosophical in purpose. Yet it has been argued that universities have lost the claim to a philosophical exemption because they file patents, exercise patent rights, and receive fees for licensing and royalties. Sederoff's paper can be found beginning on page 71.

Jack L. Tribble, Merck & Co., Inc.

Gene ownership versus access: meeting the needs was discussed by Tribble who pointed out that patents are vital for industrial research incentives. He indicated that recent advances in the pharmaceutical industry made possible

by biotechnology were achieved because of the patent incentive. At the same time, he said he understands the need for public research, and sees an interdependence among industry and university researchers. Tribble discussed how policy attempts, such as the Bayh-Dole Act, to solve the problems of research access have been positive in intent, but largely unsuccessful. This legislation intended to make information and germplasm openly available for research purposes, but instead there has been a federal policy shift towards patents and away from putting information into the public domain.

He explained that Merck's policy is to make materials available for research tools distinct from licensing for products. Merck supports a policy of licensing of patented inventions for research use, separately from licensing for commercial development of products for sale. For example, the company has developed the Merck Gene Index Project, a catalog of sequence data, which will make cDNA sources available to all scientists. He indicated that Merck wants to foster collaboration among commercial laboratories and academic and governmental laboratories to allow science to advance, foster competition among commercial labs, and speed discovery of new products to benefit the public. See page 97 for Tribble's paper.

Leanna M. Lamola, Attorney

Lamola spoke about intellectual property rights in agricultural genetics and their function in industrial agriculture. She indicated that identity-preservation is one type of an end-use oriented marketing system that is changing the structure of modern production agriculture. Intellectual property rights play a central role in identity-preserved systems, such as Calgene's Flavr Savr™ tomato, because they allow rights holders to reduce investment risk, obtain premium prices, preserve the identity, and control the use of value-added factors in downstream or upstream arenas. According to Lamola, production contracts are the main mechanism by which producers will participate in identity-preserved systems. The producers may decide to fund the development of identity-preserved varieties through research agreements or other strategic alliances with private or public organizations. Such activities will add to the need to re-examine the traditional relationship between the land-grant university and agriculture.

Lamola suggested that there are a number of factors that can impact a contract producer's ability to obtain higher returns, including relative bargaining power. Recently, some contract producers have organized into associations to improve their bargaining position. Perhaps the most well known is the National Contract Poultry Growers Association, which has lobbied for state and federal legislation designed to prohibit unfair practices by integrators. Lamola's entire paper can be found beginning on page 87.

Jose Luis Solleiro, National University of Mexico

Solleiro, who spoke in this plenary session and the third one, talked about defining and ascribing ownership to genes and farmers' rights. An issue close to the heart of ownership is valuation, he said. For example, how do you sort out the proportion of value added by an inserted gene from a plant found in a developing country when engineered into a plant variety originally developed in a long-term breeding program at a public institution supported by public U.S. funds? Today in agricultural biotechnology we are moving more toward an approach of putting different pieces of knowledge together, which is necessary to move forward. But how do we sort out ownership, credit and compensation?

According to Solleiro, it is essential to improve the legal framework to deal with these issues at all levels and to build domestic capacities to identify, conserve and use genetic resources, and better negotiate the terms of future agreements. See page 109 for his paper.

Access to Genes : Public and Private

The third plenary session presented four different viewpoints on the issue of public and private access to genes of importance to agricultural biotechnology.

Henry L. Shands, United States Department of Agriculture

Shands spoke about access: bartering and brokering genetic resources. He indicated that ownership of genetic resources has become a vocal issue surrounding the Convention on Biological Diversity, ostensibly because of the pharmaceutical industry's profits from drugs developed from medicinal plant sources. However, much of the movement to curb the exodus of plant genetic resources from developing countries came as a result of developed countries intellectual property laws giving companies a legal basis to protect their varieties and inbred strains for hybrid production. He said that the most severe problem associated with the international access to genetic resources is that discussions are held in a political rather than a scientific context, without a logical concern for such issues as food quality and safety. The world's agriculture is inextricably connected, and it is not sufficient to think about our own country's system. United States Department of Agriculture has a policy of free exchange under the National Plant Germplasm System. However, with increasing restrictions to access of genetic information, the sharing of information by scientists will become a more serious problem in the future. He argued that the international community should provide open access to all genetic resources for food and agriculture, engage Material Transfer Agreements (MTAs) to enable research and breeding with the material, facilitate a brokerage system for this exchange, establish a tracking system and compensation mechanism for germplasm, and promote a bartering system in which access is provided in exchange for training and/or technology. In addition, he said that an international fund is needed to support biodiversity. See page 117 for his paper.

Peter R. Day, Rutgers, the State University of New Jersey

While discussing the impact of patents on plant breeding using biotechnology, Day admitted that the introduction of plant variety rights encouraged the development of private sector plant breeding. Although this has led to a decline in academic breeding programs, there remain many opportunities for germ-plasm enhancement research in our universities. Biotechnology patents are bringing about similarly profound, but far more complicated changes. Enhancement through transformation almost always involves the use of patented genes and/or methods. Although investigators are free to use patented properties for research, there are severe constraints in the developed as well as the developing world to using them in agriculture to benefit farmers. Many believe that the constraints are justified as the price for protecting intellectual property. He noted that academic scientists are becoming just as involved as their colleagues in industry.

The extent of patenting single genes or enzymes that are part of a larger system of research has made basic research extremely complex. For example, Rutgers' scientists developing new cultivars for field tests have to take existing patents into account and have each interested party agree to use under a license that specifies payment required. Several of these licensing agreements may be necessary for one experiment to be conducted. The scope and extent of patenting is growing within industry and within U.S. universities and other public research arenas. For example, at Stanford University there is one patents officer for each ten faculty members. He agreed with Sederoff that universities are involved in research for profit, and he cautioned that scientific research with a specific product in mind can be a shortsighted approach. A related access issue arises in business decision-making with reference to minor crops. If a company is focusing only on top-priority opportunities, it may close down access to genes important for minor crops or for what seems to a company to be a marginal opportunity, but which might meet some important public need. The question can be posed as: How can we ensure that the public benefits in a wide array of ways through access to discoveries? His paper begins on page 79.

John G. Kinsman, National Family Farm Defenders and the Wisconsin Family Farm Defense Fund

During his presentation, Kinsman spoke about farmers' rights: what is fair? He focused on the rights of farmers who feel a strong need for self-determination and now despair about their situation. He asked the question how can channels of communication between farmers and biotechnologists be opened up? He answered by saying that long term talks and constructive cooperation are needed and condescending attitudes towards farmers and hasty decisions should be avoided. He also said that IPR should be considered a lease rather than a right. What are the financial implications? What are the impacts of IPR? He feels that farmers were misled by those who assured them that agricultural

chemicals are safe, in light of the reported contamination of well-water in the U.S. by these products. He commented how can we as grassroots farmers and consumers be assured of proper control and safeguards to our livelihood in agricultural biotechnology? He pointed out that the ethical and moral implications of emerging technologies need to be thoroughly examined and weighed for their impact on cultures and economies. Will the economic and lifestyle impact be progressive and stable, or will the impact be devastating to certain regions, countries or cultures? He wanted to know, as an average American citizen, how his basic rights will be affected. What safeguards are in place or need yet to be developed to protect the health of people and the environment in the release of genetically engineered bacteria and other life forms? See page 105 for Kinsman's paper.

Jose Luis Solleiro, National University of Mexico

Speaking again during this session, Solleiro discussed IPR: key to access or entry barrier for developing countries. He indicated that IPR has become a basic objective of companies seeking to commercialize biotechnology derived products. This renewed interest in IPR has already triggered unilateral actions, such as those undertaken under the U. S. Trade and Tariffs Act as well as multilateral negotiations within the World Intellectual Property Organization and the General Agreement on Tariffs and Trade (GATT). Intellectual Property Rights played an important role in the North American Free Trade Agreement (NAFTA) negotiations. Many developing countries have already adopted modern IPR legislation, granting protection for most biotechnology developments. Solleiro described the Rio Convention on Biodiversity which granted access to genetic resources to individual governments, depending on their own domestic policy. He made the important distinction, though, that "free access does not mean free of charge." Conventions, powerful countries and big companies claim that developing countries have protective rights, but he explained they cannot enforce them. He gave a hypothetical example illustrating how a small company in Mexico would not have the resources to sue a large multi-national company for infringement. He indicated that the system is still incomplete, and in its present state the IPR system benefits large multi-national corporations who receive patents and lawyers who sift through the mass of legal intricacies created by the system. From the perspective of developing countries, concern for protection under an IPR system takes a back seat to domestic concerns over such issues as a weak domestic industry, research limitations, conservative attitudes, poor economy and the lack of concern over agricultural education. He concluded that, for a country like Mexico, a protective system of IPR is not sufficient to allow access to biotechnology innovations. There should be a national commitment to agriculture research and development, and an adequate legal framework to handle international technology transfer. Solleiro's paper begins on page 123.