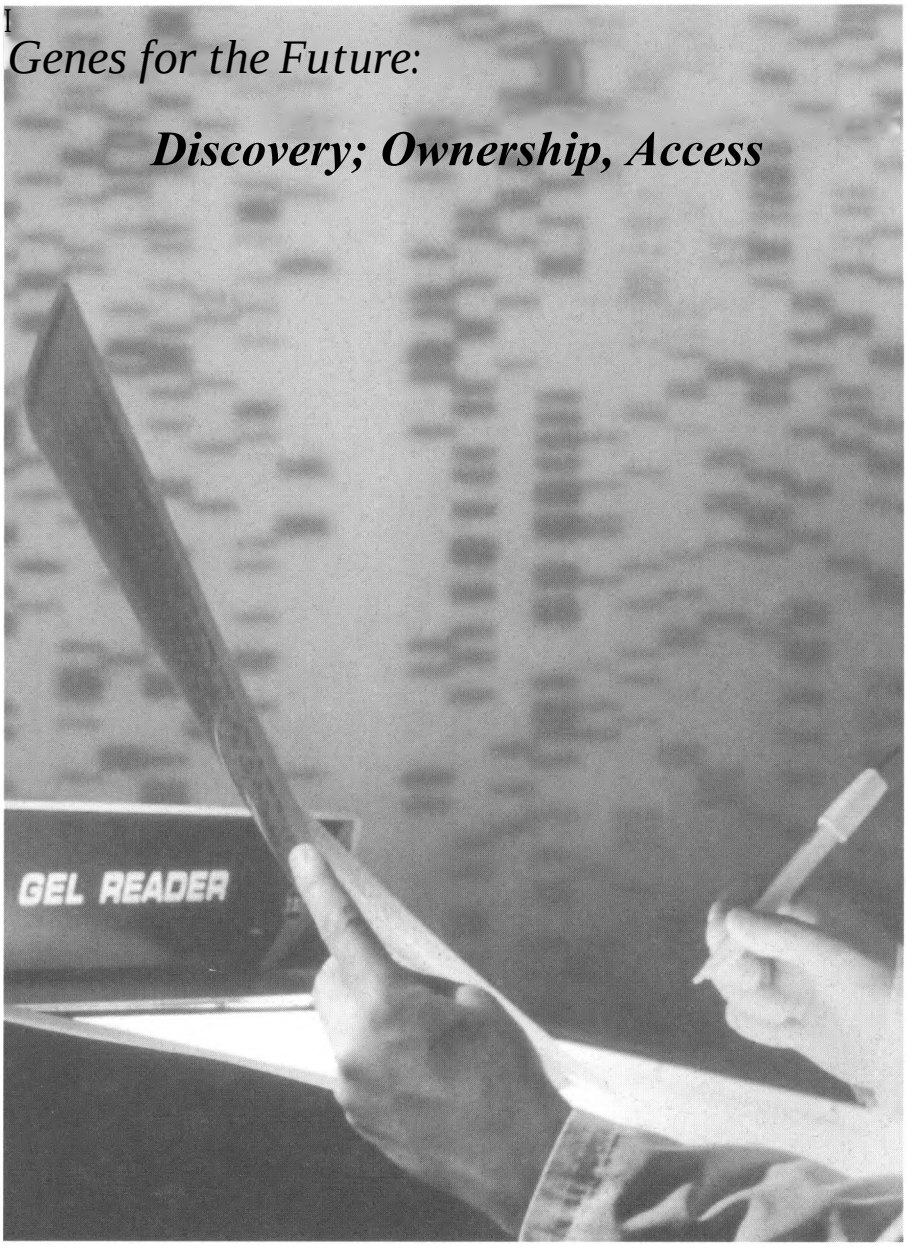
NABC Report 7

I

Genes for the Future:

Discovery; Ownership, Access



NATIONAL AGRICULTURAL BIOTECHNOLOGY COUNCIL REPORTS

NABC Report 7

Genes for the Future: Discovery, Ownership, Access

Edited by **June Fessenden MacDonald**

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NABC Report 7
Genes for the Future: Discovery, Ownership, Access

The National Agricultural Biotechnology Council provides an open forum for the discussion of issues related to the impact of biotechnology on agriculture. The views presented and positions taken by individual participants in this report are their own and do not necessarily reflect the views or policies of the NABC.

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National Agricultural Biotechnology Council

Providing an open forum
for exploring issues in
agricultural biotechnology

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The success of the seventh annual National Agricultural Biotechnology Council (NABC) meeting is the result of the hard and careful work of the Meeting Coordinator, Carrol Lewis, and the Organizing Committee at the University of Missouri-Columbia, the host institution: G. Michael Chippendale, chair, Bill Folk, Bruce Bullock, Doug Randall, Gary Johnson, Ken Schneeberger, Bill Day, Mike Roberts, Don Riddle, Perry Gustafson, Mike Misfeldt, Ed Coe and Roger Mitchell. NABC gratefully acknowledges the important role played by the workshop facilitators: Chuck Fluharty, Daryl Hobbs and Joe Polacco; and the workshop recorders: Rite Gerke, Judy Gieselman and Donna Vaught. Special recognition goes to the efficient conference service provided by Karen Powell and her staff, especially Linda Langston.

The cooperation received during the production of this report — from the meeting organizers, presenters, workshop chairs and participants — was great and is sincerely appreciated.

Very special thanks go to the NABC staff, who each played a special role in the production of this report: Loren Mooney, who has moved on to pursue her writing career, for her help assembling the workshop reports; Kate O'Hara, now in Arizona pursuing her interest in design in the ergonomic field, for her many years of superb design, production and administrative work for NABC, and Jane Baker Segelken, who although new to her position, provided copyediting assistance and oversight of report details.

To all the members of NABC, your support, advice and friendship is gratefully acknowledged.

June Fessenden MacDonald
Executive Director, NABC
Editor

PREFACE

With the completion of this volume and after six years with the National Agricultural Biotechnology Council, I will be stepping down as Executive Director of the NABC. Jane Baker Segelken, Executive Coordinator, will assume the oversight of the NABC office and its day-to-day operation. As it grew from the original four institutions: Boyce Thompson Institute for Plant Research (BTI), Cornell University, University of Iowa and University of Califomia-Davis, to its present membership of 24,1 have been privileged to work with some of the leaders of agricultural research in the U. S. and Canada. Throughout my tenure, I have worked closely with the several chairs of the NABC, Roger L. Mitchell, University of Missouri-Columbia; Robert G. Gast, Michigan State University; Bill R. Baumgardt, Purdue University; and Ralph W. E Hardy, Boyce Thompson Institute. Following his retirement from BTI, Ralph Hardy, cofounder of NABC in 1988, will be assuming the newly created position of president of NABC moving the organization into a more proactive stage.

However, the goals of NABC remain as stated in the preface of NABC Report 1:

> "The Council, through sponsorship of meetings and workshops, and NABC Reports, strives to facilitate the development of policy recommendations for the safe and efficacious development and use of agricultural biotechnology products and processes for the benefit of society; to involve all interested and affected groups in a holistic, rather than disciplinary- or constituency-oriented evaluation of the potential impact of biotechnology on agriculture and development of policy alternatives; and to promote increased understanding of agriculture and biotechnology."

NABC from its first annual meeting at the University of Iowa in 1989 through its seventh at the University of Missouri-Columbia has constructed its meetings around a common format: a series of lectures to provide a common informative base for dialogue in the subject area workshops, which are the heart of NABC meetings.

As is common to all of NABC Reports, this volume offers in Part I a general overview to provide the reader with some of the flavor of the meeting as well as a short synopsis of each of the lectures and a summary of the consensus recommendations developed by the workshop participants. The full workshop reports, prepared by the co-chairs and reviewed by all workshop participants, are presented in Part II. For those who want more specific information, the keynote addresses and the topical lectures are in Parts III and IV, respectively.

Since this Report is not a traditional proceeding, I have taken the editor's prerogative and organized the topical papers in Part IV to provide the reader with a view of the many issues surrounding intellectual property rights (1PR) from the perspective of the laboratory scientist to the field researcher to the producer of a crop. These papers are followed by perspectives from a member of industry, a farmer and a representative from a developing country. The final two papers focus on the several international efforts of ownership and access to genes and genomic material, and the South-North debate.

NABC hopes that this report, representing the range of perspectives on gene discovery, ownership and access, will contribute to increased understanding of the various issues, the different viewpoints on these issues, and provide a foundation for the reader's meaningful dialogue for addressing these critical issues in the agricultural biotechnology area.

I wish you pleasant reading and productive dialogue.

June Fessenden MacDonald
Executive Director

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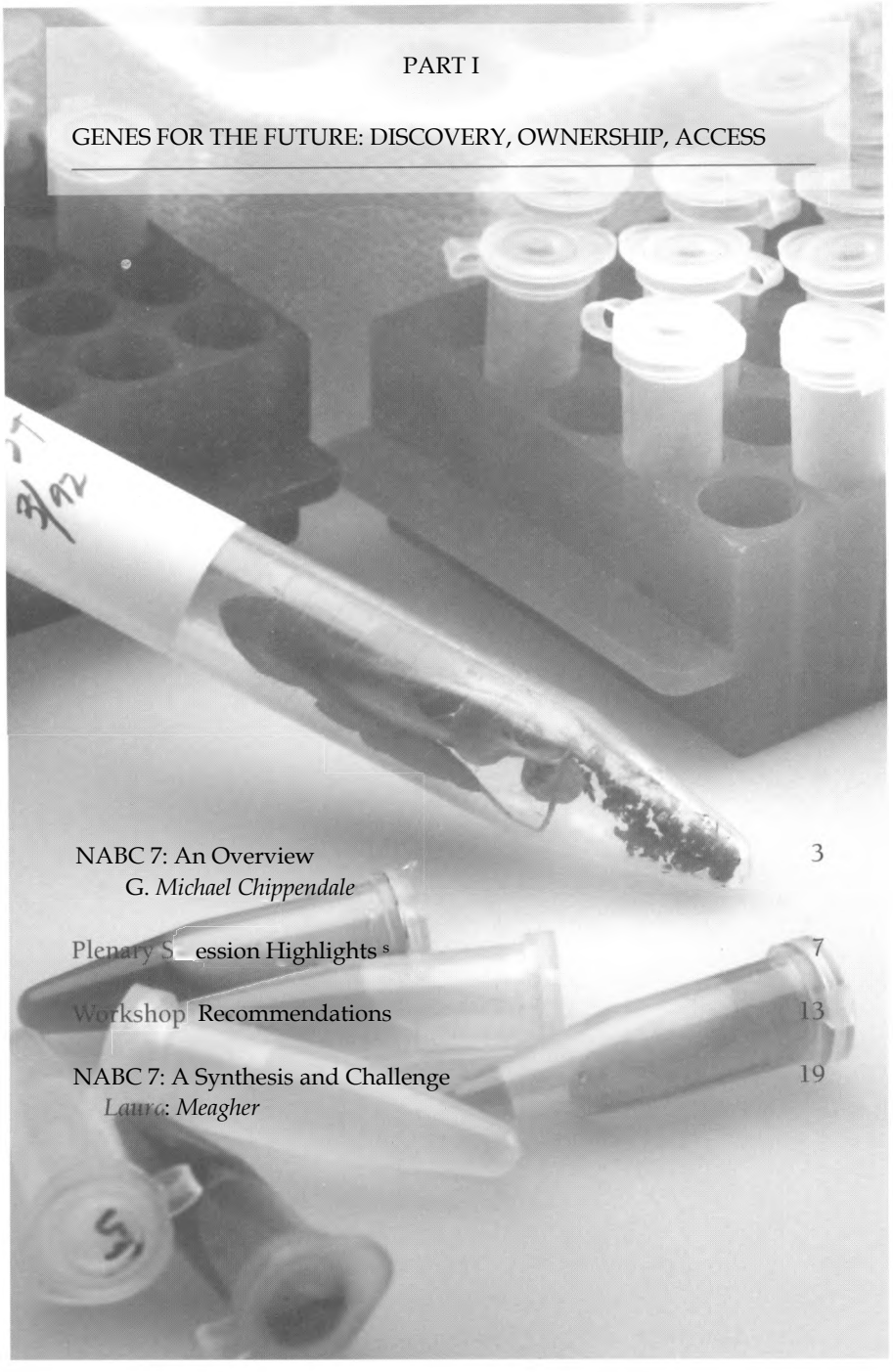

PART I

GENES FOR THE FUTURE: DISCOVERY, OWNERSHIP, ACCESS

NABC 7: An Overview

G. **Michael Chippendale**
Chair, NABC *1 Planning Committee*
University of Missouri-Columbia
Columbia, Missouri

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 f 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 (1PR) 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 1PR 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 1PR 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 germplasm 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. Solliero's paper begins on page 123.

Workshop Recommendations

Participants in the three workshops, which are the heart of the NABC meetings, formulated recommendations for policymakers, participants and readers *on research policy issues, competing rights,* and *the role of governments and public institutions* related to gene discovery, ownership and access. The participants also considered how genetic discoveries should be exploited to maximize the public good and benefit society. Plant, animal and microbial aspects of agricultural biotechnology were considered from national-international, developed-developing countries, and public-private perspectives.

Research Policy

(See page 29 for the complete report.)

University Agenda-Setting

- NABC *should convene a forum to establish the public research agenda for agricultural biotechnology and identify high priority research tasks requiring attention.*
- *NABC should compile a repository of biotechnology experts and serve as a referral agency to outside organizations.*
- *NABC should* survey *its membership on the relative mix of industry- and public sector-sponsored biotechnology research at land-grant universities to provide baseline data to help inform the debate.*

Research Exemption

- *NABC should undertake an educational program aimed at clarification of the experimental use exemption in patent law.*
- *Universities and government agencies should be granted a research exemption as not-for-profit organizations in order to allow such groups to use patented technology in research for noncommercial purposes. A possible mechanism for such an arrangement would be the granting of a royalty free license to use patented inventions.*

Patent Scope

- *NABC should lead a public discussion on patent scope, recommend reasonable limits, and build consensus that patents should be narrow in scope.*
- *Strong utility requirements must be achieved before patents are granted.*

North-South Relations

- *NABC should compile and synthesize the experiences, good and bad, of NABC members on exchanges of information and germplasm between universities in developed countries and universities in underdeveloped*

countries. Based on this information, NABC should develop a position paper on the principles and procedures of fair exchange.

- *NABC, in partnership with farmers and all others involved in producing and utilizing agricultural products, processes and information, should find ways to fairly and equitably recognize contributions of land races and indigenous plant populations and knowledge. Such ways may include educational programs and pamphlets.*

Competing Rights

(See page 37 for the complete report.)

- *There is a need to manage the basic gene pool for the common good. There has to be cooperation between the private sector and the public sector to work for the common good. Therefore it is the recommendation of this workshop that the public sector increase efforts to determine and set long term policy with broad constituency involvement, e.g., farmers, local government, universities, consumer groups, NGO's and industry. The private sector should develop products in an environment compatible with genetic preservation and access.*
- *There should be formal recognition by potential users of biological resources of rights to control over and compensation for use of biological resources not only by individuals and nation states but also by local communities, cultural groups and regional groups.*
- *At forums such as the Fourth International Technical Conference on Plant Genetic Resources in Germany in 1996, and at the next meeting of the Conference of Parties to the Convention on Biological Diversity, November, 1995, in Indonesia, there should be encouragement of equitable and enduring agreement among those with rights in biological resources and between those with rights and potential users, which should include education of all parties on fundamental issues and long-term funding of biodiversity conservation.*
- *NABC meetings should be organized to provide more background information and direction to participants, including availability of expertise in legal, social and biotechnology issues; and should actively recruit participation of a broader range of views. This improvement should lead to more useful recommendations.*
- *NABC member institutions should establish outreach programs on biotechnology and associated intellectual property issues.*
- *Clarify the "research exemption" for utility patents for use by public research institutions.*
    a. *Gene sequence information (all uses),*
    b. *Process information (e.g., the enzyme Taq polymerase as a tool for research),*

Specifically:

c. *A specific plan for action proposed by one participant, but not presented here as a consensus of the workshop was: Universities should challenge the ability of patent holders to restrict research at universities (using patented technology), and*

d. *If the challenge is unsuccessful, they should lobby Congress to change the law to allow such research.*

Role of Governments and Public Institutions

(See page 43 for the full workshop report.)

Need for Biotechnology Education

Access

- *Each school or college of agriculture should identify biotechnology specialists who can be contacted by field/county extension staff for information, program development and program delivery.*
- *NABC should work with extension leadership to include biotechnology awareness and education in extension education programs.*
- *NABC should identify and encourage development of needed educational materials (e.g., brochures, e-mail bulletin boards, videotapes, etc.).*
- *NABC should encourage testing and evaluation of commercial biotechnology materials and products, including cost-benefit analysis, in public sector institutions.*
- *NABC should encourage input from user advisory groups to assist in setting applied biotechnology research priorities.*

Public Awareness

Undergraduate education

- *NABC should encourage incorporation of ability to understand and interpret biotechnology in undergraduate "core" curricula, with special attention to risk assessment, technical, ethical and socioeconomic issues.*

K-12

- *NABC should publish a list of educational materials on biotechnology.*
- *NABC should encourage state and local teacher groups to hold workshops on biotechnology.*
- *NABC should develop youth education programs,* using *programs such as 4-H as a means of biotechnology education.*
- *NABC should work with vocational agriculture teachers and support efforts to incorporate biotechnology training in vocational agriculture curricula.*

Opinion leaders/public

- *Scientists should appreciate the importance of and receive training in media relations.*
- *NABC should encourage TV programming (Discovery, NOVA, etc.) and other forms of mass media-based education to provide information to the public on biotechnology.*
- *Through its member institutions, NABC should encourage workshops, conferences and other public forums designed to include the broadest range possible of constituent groups in an on-going dialogue on biotechnology issues.*

General

- *NABC should involve educators in programs such* as *this meeting and provide specific, more targeted workshops for teachers to develop educational materials.*

Intellectual Property Rights

- *Graduate and undergraduate curricula should include specific training in intellectual property rights and issues.*
- *NABC institutions should develop a clear policy describing the rights and responsibilities of graduate students regarding intellectual property rights.*
- *NABC should act as a catalyst to develop a curriculum addressing intellectual property rights and ethical issues.*
- *NABC should act as a clearinghouse for educational programs and institutional policies on intellectual property rights.*

Access to Intellectual Property from Genome Analysis and other Aspects of Agricultural Biotechnology

- *Policy for release of intellectual property by public institutions should be based on a mandate to promote the public good rather than motivation to increase institutional financial resources.*
- *Public advisory groups should have input into setting policy for release of intellectual property by public institutions.*
- *Public policy should be devised to maintain broad access to tools of biotechnology (germplasm, genes, methods) developed at public institutions.*
- *Public law should provide a more liberal research exemption on patented intellectual property.*
- *The courts should apply anti-trust laws to ensure competition in the biotechnology industry.*
- *The term of ownership of patented intellectual property should be re-examined with the goal of balancing economic returns to investment versus opening the knowledge for future productivity and innovation.*

- *While there was not unanimous support for this recommendation, many work-shop participants felt that the Patent and Trademark Office should issue utility patents only on the final product (plant genotype), rather than individual components or processes (e.g., genes or transformation methods).*

Need to Identify and Involve Stakeholders in Defining the Public Good

- *NABC, in collaboration with land-grant and other universities, and organizations such as CAST, should sponsor a national panel of stakeholders in agricultural biotechnology (farmers, consumers, environmental groups, government, seed trade associations, etc.) to define the "public good"; assess the effects of intellectual property rights on technology transfer and utilization; and issue a report.*
- *NABC should encourage greater participation of legislators and other government officials in NABC annual meetings.*
- *For public input to have impact, the public institutions should seriously listen to comments and be held accountable to public advisory groups.*
- *Appropriate research roles for the government and public institutions include enhancing the use of biotechnology in minor crops to promote diversification for family farmers, promoting new and innovative* uses *of agricultural commodities through biotechnology, and promoting environmental responsibility in the use of agricultural biotechnology products. These roles can be implemented only if public funding for agricultural biotechnology research is increased.*

Research Incentives

- *There should be motivation provided for fundamental and applied research, for commercialization of results from research and for exchange of information with other researchers, teachers and extension faculty.*

Reinvestment of Profits from Publicly Funded Research

- *Distribution of royalties and license fees from publicly funded research should be returned to the institution/unit that developed the intellectual property, to be reinvested in research.*

Research Regulation and Safety

- *Products posing different levels of risk should be treated with different levels of stringency in oversight. Care in regulation is of special concern regarding environmental release of genetically modified organisms with the ability to propagate in the wild.*

IS ABC 7: A Synthesis and Challenge

Laura Meagher
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New Brunswick, New Jersey

There have been many good discussions throughout this meeting, and some very good speakers have made targeted comments that brought out the breadth of the issues involved. The workshop sessions have been good and there were fascinating individual conversations over meals. It is a tall order for me to try to pull this wealth of interaction together. 1 have decided to go back to what the organizers cleverly came up with originally — Discovery, Ownership and Access. I want to talk about some issues I see in those areas, and then at the end bring out some synthetic points or challenges that I see. My only reservation in talking about Discovery, Ownership and Access is that, as I was writing myself notes, 1 saw that the initials are D-O-A, possibly not a good omen.

Discovery

In *Discovery,* some of the questions to be asked are: Who discovers? With what purpose? How is the discovery process funded, and in what context does it take place? A key issue in discovery, of course, lies in the health and well-being of research, the discovery process in particular. As Dick Flavell described so well in the opening session, the pace of discovery related to genes is accelerating rapidly. The sharing of useful information that we have been doing in this meeting is just one example. Maybe we will find out more about minor crops or developing country crops as we learn about major crops. The prospects are very exciting. Breeders may exchange information more readily. There may be a real explosion of both knowledge and ability to implement. Ron Sederoff described the example of mapping the loblolly pine that would have been impossible two years ago and unthinkable ten years ago, but now it is being done. The question is: Will this pace continue? Will it accelerate? Or will it slow down due to obstacles or to costs exacted by intellectual property rights and the standard operating procedure of our university/industry/government interface as it exists today?

We also heard some examples of work that is not going to be done. Forest tree genetics-environment interaction on a large scale is fundamental work that will not be done because of cost. Many issues exist that are fundamental to research policy, and many working papers have made recommendations accordingly. Can we develop and implement research policy that will protect discovery in agricultural biotechnology? The recommendations from the workshops tend to center on: ensuring the survival of long-term basic research and somehow inserting social responsibility into the agenda-setting process, facilitating discoveries that will ultimately benefit the public.

Ownership

In *Ownership*, some of the questions to be asked are: Who owns what? What is the "what" that is being owned? What are the overriding traditional principles governing ownership, and are there any new paradigms for principles to govern ownership? Are there new opportunities for sharing? In whose best interest are ownership practices right now? Is the public benefiting and is there equitable treatment? A central need in ownership is to address what often appears to be the conflict between social good and private gain. That dynamic tension has come up over and over again and will continue.

There is a whole cluster of concerns over possible negative impacts of ownership on universities or on the research enterprise. Kathleen Merrigan, Ron Sederoff, Jack Tribble, Leanna Lamola and others raised relevant questions. Are we going to skew the agenda for what research is done? If we move towards shorter term research, or research that fits with private sector gain or that is shaped by consideration of intellectual property rights, are we using up our intellectual capital? We have been building useful discoveries on the basic work that has been done in the past; what do we do when we run out of such research results? Similar questions arise in education. Are there conflict of interest problems? What is the cost of not doing other kinds of research? Lamola brought up commodity groups' questioning of intellectual property rights. Those groups have always questioned some of our newer technology transfer approaches. It is an old controversy, but maybe there are some new lessons to be learned.

A key issue is the ownership system and the universality of its appropriateness. Merrigan asked why we are so anxious to have all developing countries blindly take on our technology transfer/intellectual property rights system. Jose Luis Solleiro pointed out significant differences between the U.S. and developing countries. For example, developing countries face different kinds of markets, domestic industry, research strengths and governmental priorities. The interface between the U.S. system arid intellectual property systems that are operational in other countries needs to be looked at. What can be done to make such an interface work? What kinds of understandings and partnerships do we need to reach?

Another issue close to the heart of ownership is valuation. How would you sort out the proportion of value added by an inserted gene from a plant found in a developing country placed into a plant variety originally developed in a long-term breeding program at a public institution supported by public U.S. funds? Where is the incremental value? Where is the proportionality? John Kinsman and Solleiro both talked about this. How do you put a proportional value on knowledge? Today in agricultural biotechnology we are making the necessary move toward an approach of putting different pieces of knowledge together — which is crucial to forward movement — but how do you sort out ownership, credit and compensation? Compensation issues are key to ownership.

And, finally, and quite basic to the theme of ownership, what is covered by a patent? What is a novel gene? As we learn more about similarities among different species, how different do sequences have to be to be patentable? What is the appropriate breadth of a patent? 1 was told by a CEO of an agricultural biotechnology company a few days ago, when he heard 1 was to make this presentation, "Make sure to tell them that we have to have broad patents, or else there's no incentive for industry." And what we heard at this meeting was: "Be sure you have narrow patents so there's incentive for everybody." There is some lively controversy there. The scope of patentability and ownership is especially important when you consider, as Lamola discussed, the identity preserved systems or other systems when at any point in the whole, complex process of production, upstream or downstream, there might be some "moment" of intellectual property protection that will have an impact on the rest of the whole stream. Is that a strength or a vulnerability, and what are the implications? We have heard recommendations spanning the wide spectrum of "do not challenge the patent system, it works" to "do away with the patent system."

Again, there are interesting differences in points of view. Clearly, it seems what everybody wants is some examination of intellectual property rights related to genes, related to agricultural biotechnology, and related more broadly to the public good. This is going to entail looking closely at public-private interfaces and different roles of different institutions. There were some recommendations about that and about roles that the NABC might play as well. Another thought that surfaces is that distribution of profits and benefits should be equitable, whatever that truly means. One workshop group suggested that there will not be one easy answer; instead, the best distribution is probably going to be based on people coming together and negotiating what is equitable. That is probably true on a variety of levels.

Access

As far as *Access:* Who has access to what? What traditional principles guide us in access? Is there a need for new principles? Can we go further in making access equitable? Can we maximize the public good through approaches to

access? Access can refer to researchers, research tools, and in some sense it can also refer to the public's access to the products ultimately arising from research. That last idea is a worthwhile sub-theme to keep in mind. Obviously, one of the big points that caught on and was phrased in many different ways by the workshop participants is some sort of "research exemption." That seems to have struck a real chord. However it is phrased or however it is implemented, that idea of preserving freedom of inquiry and investigation and curiosity-driven research in our institutions is important, even knowing that our institutions also engage in technology transfer. Preserving that capability seems to be one of the heartfelt responses of the conference. The NABC may well have a role in clarifying that situation, as well as specifics on materials transfer agreements and other agreements. The Association of University Technology Managers (AUTM) has clearly done a great deal in this area, and there seems to be a useful role for using the NABC as a dissemination vehicle.

Another issue, as Peter Day discussed from firsthand experience, is the sheer growing complexity of gene ownership. There are difficulties in access for research purposes and product development. If you have a gene, a vector, a promoter and an original cultivar all from different sources, are the university technology transfer offices ready to handle this? Is it just so mind boggling that it should stop you from doing research at the start? Do you need to start doing research and hope that you can hand it off to a company with a large regulatory staff to sort it all out later? Some kind of clarification up front is probably going to be necessary. But if we wait for a perfect, extensively legal clarification at the beginning we might not ever get going and do the research. The question of access is an important one.

A related access issue arises in business decision-making. As Day talked about, in some cases, such as the development of minor crops, the public may be a victim of cold, hard business strategies. 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 be a tangential opportunity. In fact, access to the genes might really serve some particular public component. How can we ensure that the public benefits in a wide array of ways through access to discoveries?

In relation to the access issue of management of information from genome sequencing, Flavell mentioned that the patenting of genes is very likely to inhibit the free global flow of germplasm. How are people going to handle this? How is information going to be handled? Are people going to slip things under the table, or are they going to have mammoth exchange agreements? How can exchange of information be facilitated? Tribble mentioned that the Bayh-Dole Act intended to make information available, and yet somehow that is not happening. The effect is the opposite. Merck & Co., Inc. is trying an interesting experiment by making materials available for research tools separate from licensing for products. That kind of distinction may be a very useful one.

That there is this wildly complex system within the U.S. is not enough. The complexity across international borders also needs to be tackled. It was addressed as the North-South issue in many of the workshop discussions and background presentations. Henry Shands, Merrigan, Solleiro and others discussed this in relation to the Biodiversity Convention and other frameworks. Clearly, genetic resources from around the world are going to be crucial to future progress in agricultural biotechnology. But how should farmers' rights be handled? Shands pointed out that, in the convention, parties are to endeavor to create conditions to facilitate access to genetic resources through: mutually agreed upon terms, prior informed consent, and sharing of benefits in a way that is clear up front. Those are not bad principles to live by in a variety of situations. If those criteria are reduced to practical human terms, it may actually be possible to make things work.

Solleiro also made an important distinction by noting that free access does not necessarily mean "free of cost" or "free of charge." Equitable compensation issues are related to access issues. He offered a challenging question: "How do you translate moral recognition into an economic reward?"

Recommendations were presented regarding access in some equitable form: access to genes, to technology, to information; access for researchers, university, industry, government, farmers and consumers, the ultimate beneficiaries of products. Many recommendations on something like a research exemption were presented, as were recommendations on education so that people have a voice in decision-making with input into research agendas and a role in shaping policy. Again, this all comes back to the theme of benefiting the public good. There was also a strong recommendation to work with and empower Third World farmers and indigenous peoples and countries to recapture some equitable compensation for their genetic material.

A Few Thoughts

Now that I have given a quick summary, 1 would like to offer a few thoughts that synthesize a little bit and leave you with a couple of challenges. Why do we care about genes and ownership and access and discovery? 1 think the answer is that at some level we are thinking about the public good. What are our public goals? Growth of knowledge, economic development, and a variety of benefits to a variety of publics. It seems to me that to achieve those goals, we are going to need a thriving interrelationship among discovery, ownership and access. We are going to have to optimize each, and they will be optimized more completely if each works well with the others. You can look at discovery as the engine of innovation, though I am a little worried that we are using up our fuel of past intellectual capital. The institutions that tend to drive discoveries are under pressure to take ownership, to deal with technology transfer offices and to bring in money. But they are also under pressure to provide easier access to what they discover; many are land-grant institutions with a traditional mission

of serving the public. There are some interesting, competing pressures in the discovery process.

Ownership drives commercialization. I think many people would argue that without ownership there is no incentive for companies to make products that will ultimately benefit society. Can we help self-interest become enlightened self-interest?

If discovery is the engine and ownership drives the engine, then access may be like public transit, with ideals of democracy, efficiency and equitability. Obviously, access is necessary for discovery; discovery is necessary for ownership and for access; and ownership is probably necessary in a capitalist system for the public's access to products. We are going to need healthy discovery and equitable access, yet the tricky part is the conjunction of ownership and access. Where do you benefit access at the cost of ownership and vice versa? How do you achieve that balance? As Merrigan brought up at the beginning, it is often a good idea to question even our fundamental premises. Do we need the current intellectual property system? Do we need a new paradigm? We had recommendations that NABC or others re-evaluate intellectual property rights related to agricultural biotechnology in order to make sure that we are moving towards the public good, and we asked many specific questions on patent scope and technology transfer and so on. Maybe it is useful to look at developing countries that do not have our overall system in place. I talked to someone at the National Academy of Sciences who worked with Pakistan to help that country put a technology transfer system into place, moving through various stages as a country that had not had intellectual property protection in the past. Looking at a country without our system is an opportunity to take a fresh look at why or how we do things. As we work with other countries, we can gain new perspectives on the possibilities.

One aspect of a fundamentally new paradigm, and nobody mentioned this that 1 heard, are the religious groups that are coalescing, to some degree or another, against the patenting of human and animal genes as described in a *New York Times* article in mid-May, 1995. I talked with Paul Thompson, an ethicist from Texas A&M University, a NABC member institution, who has talked with people involved who actually reflect a wide variety of motivations. One religious group may be against patenting human and animal genes for one reason, perhaps views of appropriate scope of laws of nature, while another group may be against it from a fundamentalist point of view. Yet, all these religious bodies are coming together, not for famine or war, but for biotechnology and patenting issues. In Europe, there are questions about patenting body parts and whether or not that includes DNA sequences in genes. This social and ethical dimension, which ties into education and the importance of listening to a variety of points of view, really needs to be part of the discussion, or part of our paradigm. There are some real challenges here.

One clear theme that came out all though the talks is that change is happening. The role of land-grant universities and other institutions is changing and will continue to change. The Kellogg Foundation has funded a series of 12 projects to: help land-grant universities talk to their constituencies; find out what these stakeholders want the world to be like in 2020; and figure out how the universities need to change fundamentally as institutions to help their constituencies reach that "vision." Since the world is changing and the role of land-grant universities and other institutions is going to change anyway, do we want to float along with it or do we want to help shape the change? That is a central challenge facing us in regard to the topic of this meeting.

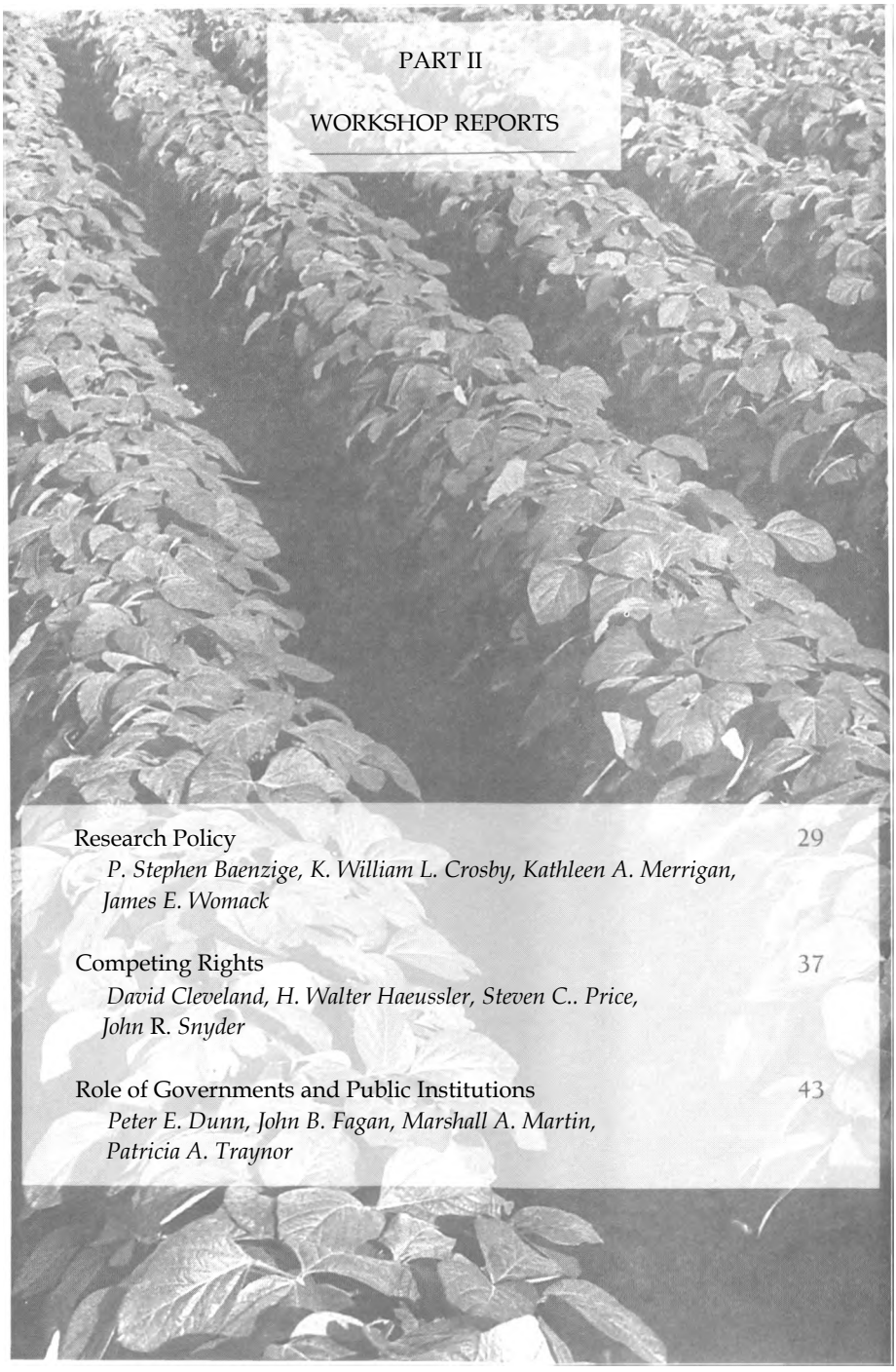
New Partnerships

One approach to addressing this challenge is to think about forming new partnerships. We have looked at the different roles of the private and public sectors. Maybe we can put partnerships together in new ways. That will mean change, issues, stress and complexity, but just maybe it is worth working through that. We have heard that the picture is not bright for research funding. That there is not a sugar daddy of federal funding out there waiting for us. We will need to get all the leverage we can and figure out how each player can complement what the other is doing. Yet in building partnerships, we have to be careful about some things such as long-term research. 1 was talking with Dick Flavell earlier, and we discussed the fact that many times when partnerships are formed they are formed for some specific purpose, and that specific purpose is likely to be short-term. This is often true of the standard university/ industry contract. We may need to form special partnerships with some mutual education paying specific attention to long-term research and exploration.

John Kinsman, a Wisconsin farmer, told us that we need "constructive cooperation" rather than "deadly competition," and I think that is true on many different levels. We have instructive examples of partnership building to consider. Merck has facilitated university, government and industry people working together to set up a database of human cDNA sequence fragments. That is one example. While it is not something to slavishly copy at all times, it is an example of people getting together to grapple with some of these issues. In Europe, there is a yeast sequencing center, a consortium where information is disseminated and shared, even though there are opportunities to patent. Again, this demonstrates that effective and innovative partnerships can be formed. We want to protect the essential, long-term effort of investigation and discovery we make at our institutions. We want to somehow nurture partnerships and "mutual responsibilities," as was said in one of the workshops. The concept of mutual responsibilities among universities, industry and government to maintain vision and mission provides a useful framework for action, 1 believe.

The Challenge

As a group, we have generated a good many recommendations. I hope that we will think about them, that we will engage others in conversation about them, and maybe even that we will pursue some of those action steps. I suspect that there is no one solution, no one thing that needs doing. I am going back to Flavell's launching of the meeting when he talked about how, as the head of an institute, he plays as many threads as he can to try to make sure the public benefits. Sometimes that means handing intellectual property out for free, sometimes it means non-exclusive licenses, and sometimes it means exclusive licenses. Pursuing several different possibilities, as appropriate, can maximize the chance of success. More broadly, I think we are going to have to pursue several approaches as we work our way through intellectual property rights and genes, and discovery, ownership and access issues, looking for ways in which agricultural biotechnology can be of benefit to the public. The task of identifying appropriate approaches to addressing our challenges is helped immensely by the dialogue we have enjoyed throughout this meeting as people with different perspectives have come together, wrestled with tough issues and worked to come up with implementable action steps.



PART II

WORKSHOP REPORTS

Research Policy

Co-chairs

P. Stephen Baenziger
Agronomy
University of Nebraska

William **L.** Crosby
NRC Plant Biotechnology Institute
Saskatoon

Kathleen **A.** Merrigan
Legislative Affairs
Henry A. Wallace Institute
for Alternative Agriculture

James **E.** Womack
Veterinary Pathobiology
Texas A&M University

The workshop began with each cochair summarizing the issues that, in his or her view, merited workshop attention. Jim Womack, an animal geneticist at Texas A&M, spoke first, and his remarks focused on three areas of concern. First, Womack reflected on plenary speaker Ron Sederoff's presentation and asked workshop participants to consider whether certain proprietary rights and patenting arrangements serve to discourage basic research at land-grant universities. Second, Womack questioned the value of patenting small DNA sequences, such as expressed sequence tags (ESTs), when we have little to no idea of how such sequences function. Do these kinds of "discoveries" truly pass the utility test of patent law, Womack challenged, and do they hinder future research endeavors? Finally, Womack argued that we may be rewarding fairly mundane research with patents, and in doing so, discouraging longer-term innovative work.

Steve Baenziger, a small grains breeder at the University of Nebraska, focused on three critical issues. First, Baenziger raised concerns about the effective length of patents. If a germplasm line is patented, or worse, patent-pending, the patentee can prohibit other researchers from using that line in any crosses that would lead to commercial development for 17 years. As it takes 12 years to develop a variety from the time the cross is made, functionally no products from other breeding efforts would be available for 29 years. Conversely, if the patentee receives his patent before he has the commercial product to sell, the development time counts against the patent duration. Second, Baenziger

questioned the patent notification process. There is a time lag between the time the patent is published and when it is filed. If a researcher uses knowledge that is not "patented" in this intervening period, only to find out later that it is patented, he or she cannot make a commercial product without the patentee's approval even though he or she was working in good faith. Baenziger cited the silicon fiber transformation technology as an example of this problem. Finally Baenziger discussed the effect of patents and other intellectual property rights (1PR) on germplasm exchange. He stressed the freedom to operate. He pointed out the irony of the current system, arguing that if he releases a line and does not protect it, someone else can protect a derivative which effectively may prevent him from using the original line. The compounding aspect of this issue is the North-South relations where his germplasm donors may not understand his need to file "defensive" patents.

Presenting her "top 10" list of problems for workshop deliberation, Kathleen Merrigan, a policy analyst with the Henry A. Wallace Institute for Alternative Agriculture, noted that the first four problems on her list were not specific to patents but exaggerated by them. Those problems are:

1. Accelerating Bt *(Bacillus thuringiensis)* resistance;
2. Excessive industry influence on university research agendas;
3. Lack of public accountability in the land-grant system due to failure to enact strong conflict of interest and public disclosure guidelines; and
4. Uneven regulatory controls.

The remaining six problems are, Merrigan claimed, outgrowths of the current patent system, and she presented them in the form of questions:

5. Are patents akin to R&D taxes in that they simply raise the cost of research overall?
6. Are some patents too broad (e.g., species-wide claims) or inappropriate (e.g., altering one amino acid only) and ultimately hinder research?
7. Should we worry that defensive patents are having an adverse impact on science?
8. How do we reasonably recognize and reward the germplasm contributions of the South and of farmers?
9. Do we need to formalize a research exemption under utility patent law akin to what exists under the Plant Variety Protection Act? and
10. Should universities patent or should we design a new system that puts land-grant university discoveries into the public trust?

Focusing on four specific areas, Bill Crosby, from the National Research Council in Saskatoon, Saskatchewan, echoed many of the concerns raised by the other speakers. First, he discussed the lack of a "fence" between "R" and "D" funding and the role patents can play in fusing these together. Second, he

urged workshop participants to consider innovative arrangements to maintain critical scientific information in the public domain. To illustrate, Crosby cited the British consortium effort to unravel the yeast genome, now 50 percent complete, and its commitment to keep all information in public hands. Crosby challenged U.S. scientists to do the same with the *Arabidopsis* genome and similar undertakings. Third, Crosby talked about problems of herbicide resistance and how patents drive universities to focus research on herbicide resistance at the expense of basic weed science because patents and other financial awards dictate the agenda. Finally, Crosby described the incremental nature of most discoveries, and asked workshop participants to consider how we go about compensating inventors for contributions made to a "discovery" that precedes the patent award. He cited the Calgene Flavr Savr™ tomato arrangement with growers as a way a company can, in a small way, compensate farmers for their development of characteristics that give birth to patented genes.

Priority Issues

After listening to the speakers, workshop participants divided into four subgroups and began the process of identifying key issues. At the close of the first day, four issues emerged as top concerns across all subgroups: university agenda-setting, research exemption, patent scope, and North-South relations. The following day each subgroup identified possible recommendations to propose to the entire workshop. A number of recommendations identified by individual workgroups achieved consensus during the final collective Research Policy workshop session and were presented to meeting participants as final NABC recommendations. Overall, workshop participants discussed the need for a more aggressive role for NABC and recommended that workshop reports be tied with action plans.

University Agenda -Setting

By large measure, the concern that dominated discussion across subgroups was whether public university research agendas are unduly influenced by industry. Researchers commented at length on the problems created by the decline in public funding for research and agreed that many problems would be solved by a larger public investment. However, participants acknowledged that the likelihood of increased public spending on research is low. In fact, participants noted with alarm that it may be difficult to maintain support for current budget levels.

Faced with that reality, participants concurred that it was appropriate and necessary for industry to fund research at public universities. Some participants argued that in an imaginary era of unlimited public funding, partnerships with industry would still make sense and be necessary for efficient technology transfer. At the same time, many participants shared personal stories illustrating the pressure placed on researchers to seek industry dollars to keep laboratories

afloat and testified to the disproportionate influence industry has on the research agenda. After considerable debate, participants agreed that there is a need to maintain some balance between public sector and industry control over research agendas to ensure the kind of freedom of inquiry essential for scientific advancement. But, this conclusion led to a host of questions. Where do we draw the line on industry investment and participation? Are hiring decisions influenced by the ability of researchers to attract private sector support and, if so, is this problematic? Are patents necessary to get university research off the shelf and into useful form? In pursuit of patent relationships with industry, are universities making a profit or simply recovering costs? Do deans have the power to control the research agenda if they wanted to? Should controls be instituted that limit the kinds and quantities of extramural funds that public universities can accept?

Thirteen issues and possible recommendations were identified and debated as ways to address the need for balance in university agenda-setting;

1. Convene public listening sessions to publicly explore this issue in depth;
2. Focus national research institutions on fundamental research, thereby avoiding duplicative efforts with industry;
3. Determine a formula for an acceptable mix of industry and public source funding devoted to research at public universities;
4. Establish criteria for partnership relationships between industry and public universities;
5. Develop a NABC national biotechnology expertise registry and referral station;
6. Set aside an unencumbered pot of money for curiosity-driven research;
7. Require matching fund arrangements between industry and public sector dollars;
8. Solicit industry funds to a national account that becomes a "third party" distributor of resources thus breaking the direct "purchasing power" of industry at universities;
9. Establish a relationship between universities and companies that puts the profits back into research;
10. Limit the conditions in research contractual agreements that now constrain research, and develop a model NABC contract;
11. Adhere to strong conflict of interest guidelines;
12. Ensure sufficient public funding for research; and
13. Insulate hiring decisions from industry sponsorships.

Recommendations

Workshop participants reached consensus on three recommendations:

- *NABC should convene a forum to establish the public research agenda for agricultural biotechnology and identify high priority research tasks requiring attention.*
- *NABC should compile a repository of biotechnology experts and serve as a referral agency to outside organizations.*
- *NABC should* survey *its membership on the relative mix of industry- and public sector-sponsored biotechnology research at land-grant universities to provide baseline data to help inform the debate.*

Research Exemption

Early in the discussion, it became clear that many researchers lack an understanding of patent law and operate under the misconception that an overall research exemption exits. Under the Plant Variety Protection Act, an exemption is granted to researchers to allow them free use of plant materials that have been issued a plant variety certificate. However, no such exemption exists in the Plant Patent Act, nor more importantly, in utility patent law under which most biotechnology inventions are protected. Several researchers shared stories of ad hoc arrangements with industry that allowed them free access to patented materials. Other researchers described blatant patent infringements, citing the analogy of resource-poor students photocopying copyrighted books while university officials cast blind eyes to this regular practice. Without exception, researchers expressed relief and gratitude that industry has not fully enforced its patent rights because to do so would seriously retard science. As well, certain universities have not enforced patents fully. A well-known example of this is the lax enforcement by Stanford University of the Cohen-Boyer patent on recombinant DNA technology that would, if enforced, require all universities to pay $10,000 to Stanford to use this basic process. Many researchers called for statutory amendment to formalize special access by university scientists to inventions, not wanting to leave such arrangements to good will. Looking into the future, many predicted that exchange problems will emerge between public universities now that an increasing number of schools, as well as industry, are seeking patents to supplement revenue.

A "two-tiered" system in the UK was discussed as a possible model for the U.S. to consider. In the UK, the government grants patents to industry but at the same time negotiates a reasonable price with patent awardees that must be extended to all public sector researchers for patented material. This and other novel arrangements were discussed, and several important questions were raised. How do public research institutions share profits with industry? Are we entering an era where universities compete with industry? Since everyone

agreed that it is unreasonable for a company to charge 10,000 times the cost of producing a patented invention as in the example cited by Sederoff, participants then asked how acceptable profit margins are determined? If universities are provided special access, will such "deals" pass on added industry costs to the guy on the street? In patenting inventions, are universities making a profit or simply recovering costs? Should a distinction be made between items researchers need over and over again and products that are a onetime purchase? Are price controls preferable to and more realistic than patent restrictions or patent elimination? How could price controls be negotiated?

Six issues and possible recommendations were identified and debated as possible ways to address the lack of an overall research exemption in patent law.

1. Seek statutory authority to lock in a research exemption;
2. Provide university researchers with a "whole hog" exemption in exchange for universities' agreement not to pursue patents independently;
3. Provide educational institutions' exemptions from process patents;
4. Establish price controls with NABC members working together to enhance the collective's purchasing and negotiating power;
5. Expand adoption of the Merck model (country sells all genetic rights to a private company in exchange for set fee and percentage of any profits made); and
6. Develop model materials transfer arrangements for use by the NABC members.

Recommendations

Two consensus recommendations emerged from discussion of the workshop as a whole:

- *NABC should undertake an educational program aimed at clarification of the experimental use exemption in patent law.*
- *Universities and government agencies should be granted a research exemption as not-for-profit organizations in order to allow such groups to use patented technology in research for noncommercial purposes. A possible mechanism for such an arrangement would be the granting of a royalty free license to use patented inventions.*

Patent Scope

Little time was spent discussing the issue of patent scope, since there was immediate agreement that recent patent awards have been far too broad. Researchers cited the Agracetus patent on transgenic cotton and the W. R. Grace & Co. application for a patent on transgenic soybeans among the examples of unreasonably broad ownership claims. There was universal agreement that it is necessary to return to the original intent of utility in patent law so that in the future patents will not be awarded for "pieces" of

information that fail to equal a whole invention. Researchers cited the Ventor/NIH human genome patent and sequencing award as an example where a patent was awarded without adequate demonstration of utility. Researchers concluded that progress in biotechnology will be threatened if the trend in awarding broad patents continues.

Four potential recommendations were identified and debated as ways to narrow patent scope:

1. Return to strong and demonstrated utility requirements for patent awards;
2. Disallow patent awards on sequences;
3. Disallow species-wide patent awards; and
4. Seek independent funding to review NABC member-held patents and their impact on innovation.

Recommendations

The group achieved consensus on the two following recommendations:

- *NABC should lead a public discussion on patent scope, recommend reasonable limits, and build consensus that patents should be narrow in scope.*
- *Strong utility requirements must be achieved before patents are granted.*

North -South Relations

Maps of the world's germplasm show many genetic resources are concentrated in developing countries near the equator. Participants discussed the North-South divide where developed countries in the North recognize intellectual property rights while developing countries in the South do not. The differing stages of development and concepts of ownership led participants to ask several questions. Is it important to maintain access to germplasm for all researchers around the world, and if so, how can this be accomplished? Is there reason to side with southern countries that prefer plant breeder rights over patents? How far do you go back in recognizing and rewarding germplasm innovation? Should the dictates of relationships between the North and South be left to the discretion of individual researchers or determined at the university or government level? Since many current exchange arrangements have developed at the South's urging, is the onus truly on the North to bring up equity issues?

Many participants concurred with plenary speaker, Henry Shands, that the U.S. has contributed a great deal back to the South in its efforts to preserve and repatriate germplasm around the world. Although germplasm exchange is not a one-way relationship, the U.S. is not recognized for its contributions. Other participants felt that looking at this issue as a "North-South" divide was too simplistic and that, at its heart, it really is an issue about how society should recognize and value the contributions of indigenous people to germplasm improvement.

Six recommendations were suggested and debated as ways to improve relations between developed and developing countries.

1. Develop institutional policies on fair exchange to help ensure equal trades by NABC members;
2. Apply the concept of "restricted use" in a way that would allow the South to use patented inventions at no/low cost but with restrictions;
3. Encourage the South to organize themselves on germplasm;
4. Educate Southern leaders on the extent of the U.S. contribution to germplasm preservation;
5. Develop a NABC paper that compiles experiences of the NABC members on North-South relations synthesizing these experiences and recommending a model of exchange for land grant universities to use; and
6. At NABC 8, include speakers from developing countries to further the dialogue.

Recommendations

The workshop agreed that:

- *NABC should compile and synthesize the experiences, good and had, of NABC members on exchanges of information and germplasm between universities in developed countries and universities in underdeveloped countries. Based on this information, NABC should develop a position paper on the principles and procedures of fair exchange.*
- *NABC, in partnership with farmers and all others involved in producing and utilizing agricultural products, processes and information, should find ways to fairly and equitably recognize contributions of land races and indigenous plant populations and knowledge. Such ways may include educational programs and pamphlets.*

Competing Rights

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The focus of this workshop was on the "competing rights" of native peoples, genetic explorers, researchers and commercial entities to genetic resources, i.e., "genes." There is a growing recognition that native peoples have rights to genes that are part of their culture, just as the discoverers and developers of these genes in the industrial world have rights. And there is appreciation of the moral obligation to find means for providing equitable compensation to all who have justifiable claims to the genes.

The purpose of this workshop was to raise and discuss issues regarding these "competing rights" and to recommend improvements in policies covering these competing rights in order to maximize social benefit — with the understanding that definitions of "benefit" differ widely among individuals and communities and will have to be negotiated between parties who are treated as equals.

Issues

The first workshop session had about 30 participants, including the four co-chairs and the facilitator. Each cochair was introduced and then presented a brief description of his perspective on the issue of competing rights. The participants were then placed into one of four subgroups, each led by one of the co-chairs, and the identification of issues began. The resulting issues/questions/comments/ideas are listed under three categories entitled *Ownership, Access* and *NABC Workshop Process and Related Issues.*

Ownership

1. The Intellectual Property Rights of local communities and indigenous farmers should be considered on an equal basis with those of industrial countries. Decisionmakers need to be informed that there are alternative ideas concerning Intellectual Property Rights and about the nature of these ideas.
2. Industry needs to educate society on how they treat intellectual property:

   Explanations should be understandable by the lay person; and

   The education should be designed to increase public trust in the process and the owners of intellectual property.
3. The Intellectual Property Rights system currently works well — leave it as it is.
4. Do away with Intellectual Property Rights entirely; they no longer provide net social benefit. In assigning value to genes, a "farmer's" investment in development of "domesticated" sources should be recognized in contrast to "wild" sources. But "local" knowledge about the use of "wild" plants and animals should be recognized and compensated accordingly.
5. Indigenous people need to be empowered to enforce their rights under biodiversity treaties both internationally and nationally. The possible means to assist this effort:

   Public defender resources in world court, and

   Easy forum for initial rights determination.
6. Does the public want to know details regarding intellectual property rights and issues, or simply that such rights exist and that they should be handled fairly?
7. Who decides what is reasonable compensation for intellectual property rights? We endorse the principle that compensation should be fair and equitable. However, we are at a loss to recommend methods to achieve this end other than through negotiation.
8. Place an international tax on natural product derivatives in order to maintain biodiversity and/or compensate owners of the genes from which such products are derived:

   Establish and international pool to dispense compensation;

   Require matching funds from the country? Industry?

   National tax or check off on product areas for research, e.g., tax on middleperson, on consumer, but NOT on farmer; and

   If there are no intellectual property rights, who will pay for innovation?

9. Biotechnology must serve the interests of the majority. Who will determine the research agenda for biotechnology and how do intellectual property rights affect this? Economic return is not equal to "success." Alternatively, how do we measure research success? Could human beings, if born after gestation in a non-human species, be ownable and patentable? How can society provide for accountability over industry to solve problems that are not discovered until they reach the consumer? For example, the peanut allergy factor.

Access

1. Broad patents limit access to genetic material for domestic and international research. Therefore a panel composed of government/university/industry representatives should be established to review this issue and recommend guidelines.
2. Reverse the trend to privatize the basic gene pool by:
   Public education;
   Providing long-term, guaranteed research funding wherein universities and NGOs [nongovernmental organizations] give up all Intellectual Property rights, i.e., knowledge is handled on a "free in, free out" basis, and a research exemption is granted to public not-for-profit research institutions for patented technologies;
   Providing long-term funding for biodiversity preservation;
   Determining how the public and private sectors can best work together for the common good; and
   Not granting intellectual property rights in genetic resources to private, for-profit institutions.
3. The research exemption for patents needs to be clarified.
4. NABC should support class action challenges to patent holders who prevent use of materials and processes for research; and strive to change basis of research exemption for utility patents from "purely philosophical" to "research for nonprofit" entities through lobbying for change in the law.
5. NABC should hire lawyers to get some type of research exemption for universities. Should there be a *pro bono* effort to challenge patents?
6. Consolidation of ownership in the food industry, e.g., turkey production, presents two potential problems: First is the vulnerability to environmental and biological hazards of food production systems dependent on a very narrow genetic base, and second are the capital requirements of such systems that control access to the most productive genotypes and reduces genetic variability within commercial populations.

Workshop Process and Related Issues

1. There is a need to educate people on issues of biotechnology and bioethics, therefore NABC member institutions should establish outreach programs on biotechnology and associated intellectual property issues.
2. NABC should develop policies and procedures among member institutions for:

   Materials exchange (NIH model);

   Cross-licensing of intellectual property rights and management within the NABC group;

   Information exchange; group confidentiality agreement?

   Go to Congress, if necessary, for antitrust relief;

   Interaction with industry groups such as American Seed Trade Association and North American Plant Breeders Association; and

   Easing the interaction of researchers at member institutions.
3. NABC should get lawyers to advise participants at these meetings. NABC should be organized by specific topics, with agendas and efforts made to include a broader spectrum of views.

Recommendations

In subsequent workshop sessions, participants discussed the above ideas and attempted to distill them into four to five recommendations that might be the basis for action by appropriate organizations. The workshop co-chairs presented the following recommendations on behalf of the participants.

- *There* is *a need to manage the basic gene pool for the common good. There has to be cooperation between the private sector and the public sector to work for the common good. Therefore it is the recommendation of this workshop that the public sector increase efforts to determine and set long term policy with broad constituency involvement, e.g., farmers, local government, universities, consumer groups, NGO's and industry. The private sector should develop products in an environment compatible with genetic preservation and access.*

For the common good to be served, policies and procedures dealing with the intellectual property rights of all stakeholders must be established. To assure acceptance of these policies and procedures, all stakeholders must be involved in establishing and implementing them.

- *There should be formal recognition by potential users of biological resources of rights to control over and compensation for use of biological resources not only by individuals and nation states but also by local communities, cultural groups and regional groups.*

- *At forums such as the Fourth International Technical Conference on Plant Genetic Resources in Germany in 1996, and at the next meeting of the Conference of Parties to the Convention on Biological Diversity November, 1995 in Indonesia, there should be encouragement of equitable and enduring agreement among those with rights in biological resources and between those with rights and potential users, which should include education of all parties on fundamental issues and long-term funding of biodiversity conservation.*

The issues before this NABC workshop are the subject of an intense international debate. The situation is extremely fluid and the issues that require resolution very real. As just one example, the control of existing worldwide germplasm collections, and access to them, is currently in flux.

While international and national agencies, and local communities are developing policies, companies and universities (gene explorers) continue to operate, albeit in an uncertain environment. However, they can attempt to identify rightful stakeholders in a gene, seek the consent of those stakeholders, establish reasonable value for the gene based on negotiation, and provide some means for compensation of all stakeholders.

While the rights of explorers, nation-states and individuals are usually covered by current intellectual property law in developed countries, the possibility of community and farmers' rights has typically not been recognized. By recognizing and valuing these rights, companies and universities can begin the process of providing equitable and enduring compensation for all stakeholders, not just those protected by current laws.

If the international community can formalize such *community* rights and *farmers'* rights, then current policies and procedures can be modified to accommodate such rights rather than establishing totally new intellectual property laws.

If mechanisms are not in place for legal recognition of community and farmers' rights and for providing appropriate compensation for such rights, companies and universities may be able to assign value to those rights and reserve funds to provide compensation at a future date when mechanisms are in place.

- *NABC meetings should be organized to provide more background information and direction to participants, including availability of expertise in legal, social and biotechnology issues; and should actively recruit participation of a broader range of* views. *This improvement should lead to more useful recommendations.*

Although there is value in independent identification, discussion and resolution of issues, much of this workshops time was devoted to educating participants on the current thinking regarding the issue of competing rights. In addition, the participants did not represent the broad range of parties with interests in this issue. The value of these recommendations is therefore diminished.

- *NABC member institutions should establish outreach programs on biotechnology and associated intellectual property issues.*

One specific suggestion is to provide the forum for public discussion of pros and cons of these issues. In this way, universities can hopefully maintain credibility as an unbiased source of information.

A second suggestion is to target decisionmakers in local communities. Make them aware of current intellectual property practices and the issues related to these practices that are being discussed by organizations involved in maintenance and use of germplasm resources.

- *Clarify the "research exemption" for utility patents for use by public research institutions.*
  a. *Gene sequence information (all uses),*
  b. *Process information (e.g., the enzyme Taq polymerase as a tool for research),*

Specifically:

  c. *A specific plan for action proposed by one participant, but not presented here as a consensus of the workshop was: universities should challenge the ability of patent holders to restrict research at universities (using patented technology), and*
  d. *If the challenge is unsuccessful, they should lobby Congress to change the law to allow such research.*

This topic generated much of the discussion in the workshop sessions, and most of the discussion after the workshop's formal presentation. The issue is becoming extremely important to university researchers as they recognize that current patent law does not contain such a broad research exemption. The enforcement of patent rights against university researchers seems counter with the intent of the patent system to encourage disclosure of a patentable idea and to educate the public. There is a perception that the philosophy of companies is changing to be more hostile and litigious towards universities.

If patent policy is intended to make inventions available to the public and to provide the means to increase societies collective knowledge base, then a clarification, and if necessary expansion, of the scope of the existing research exemption is beneficial and essential.

Role of Governments and Public Institutions

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The stated purpose of this workshop was to consider: 1. what responses are needed from government to deal with new knowledge about plant, animal and microbial genomes; 2. how the interest and investment of the public is best protected; and 3. what ways government can make investments toward useful new knowledge about genomes. The viewpoints of federal and state government, governments of other countries, land-grant universities, other public universities, and federal and state agencies were to be included in the discussion.

During the first workshop session, the co-chairs introduced themselves to the group and provided brief descriptions of their interest and involvement in the roles of governments and public institutions in genome related issues. The co-chairs personal interests ranged from direct involvement in the discovery, analysis and exploitation of genes from various organisms, to roles in assessment of public policy and technology, to development of regulations for oversight of the introduction of genetically modified organisms into the environment.

Following these brief statements, the workshop participants separated into four subgroups that were each led by one of the co-chairs. During the next two workshop sessions, subgroup participants identified, clarified and prioritized issues of concern to the subgroup, and formulated recommendations to address these issues. In the final workshop session, representatives presented a summary of the issues and recommendations from each subgroup. Following these presentations, the workshop participants discussed all of the subgroup issues and recommendations. They then merged them into a set of six areas of concern with component issues and accompanying recommendations. The participants then prioritized the six areas of concern by group vote.

Areas of Concerns

The following are summaries of the six areas of concern and the workshop participants' consensus recommendations for addressing them. Areas of concern are presented in the priority order established by the group vote.

Need for Biotechnology Education

Issue 1. Agricultural producers (farmers) require access to information on biotechnology. Extension and research personnel have a critical role in providing this information.

Recommendations

- *Each school or college of agriculture should identify biotechnology specialists who can be contacted by field/county extension staff for information, program development and program delivery.*
- *NABC should work with extension leadership to include biotechnology awareness and education in extension education programs.*
- *NABC should identify and encourage development of needed educational materials (e.g., brochures, e-mail bulletin boards, videotapes, etc.).*
- *NABC should encourage testing and evaluation of commercial biotechnology materials and products, including cost-benefit analysis, in public sector institutions.*
- *NABC should encourage the use of input from user advisory groups to assist in setting applied biotechnology research priorities.*

Issue 2. There is a need for increased public awareness of biotechnology issues. Only through education can the public be empowered to participate in debates on specific biotechnology issues and products. Education is needed at all levels — from K-12 to undergraduate curricula — to dialogue with opinion leaders. For the general public to make educated choices and decisions, they need a strong knowledge base about the technology and related issues. They need skills in evaluating information.

The researcher has the responsibility not only to do high quality research, but also to communicate clearly research results and their significance to the public. The researcher should serve as an educated, unbiased voice, available to all parties. Public institutions also have a responsibility to increase public awareness, and should work with professional organizations, community groups, farm organizations, industry and educational organizations to satisfy this responsibility.

One example of a forward thinking program is USDA's Ag in the Classroom program. Pioneer Hi-Bred's Living History Farm is also an example of the kind of educational tool that could be developed.

Recommendations

Undergraduate education

- *NABC should encourage incorporation of ability to understand and interpret biotechnology in undergraduate "core" curricula, with special attention to risk assessment, technical, ethical and socioeconomic issues.*

K-12

- NABC *should publish a list of educational materials on biotechnology.*
- *NABC should encourage state and local teacher groups to hold workshops on biotechnology.*
- *NABC should develop youth education programs, using programs such as 4-H as a means of biotechnology education.*
- *NABC should work with vocational agriculture teachers and support efforts to incorporate biotechnology training in vocational agriculture curricula.*

Opinion leaders/public

- *Scientists should appreciate the importance of and receive training in media relations.*
- *NABC should encourage TV programming (Discovery, NOVA, etc.) and other forms of mass media-based education to provide information to the public on biotechnology.*
- *Through its member institutions, NABC should encourage workshops, conferences and other public forums designed to include the broadest range possible of constituent groups in an on-going dialogue on biotechnology issues.*

General

- *NABC should involve educators in programs such as this meeting and provide specific, more targeted workshops for teachers to develop educational materials.*

Issue 3. The increasing role of intellectual property rights in academic research has had a substantial impact on graduate students and the research environment, and should thus be addressed in graduate education.

Recommendations

- *Graduate and undergraduate curricula should include specific training in intellectual property rights and issues.*
- *NABC institutions should develop a clear policy describing the rights and responsibilities of graduate students regarding intellectual property rights.*
- *NABC should act as a catalyst to develop a curriculum addressing intellectual property rights and ethical issues.*
- *NABC should act as a clearinghouse for educational programs and institutional policies on intellectual property rights.*

Current intellectual property rights laws and policies, and the increasing reliance of researchers at academic institutions on private sector sources of research support: restrict public access to genetic materials, technologies and information; limit free market competition; reduce research opportunities and innovation; limit the knowledge base; and restrict educational opportunities.

Recommendations

- *Policy for release of intellectual property by public institutions should be based on a mandate to promote the public good rather than motivation to increase institutional financial resources.*
- *Public advisory groups should have input into setting policy for release of intellectual property by public institutions.*
- *Public policy should be devised to maintain broad access to tools of biotechnology (germplasm, genes, methods) developed at public institutions.*
- *Public law should provide a more liberal research exemption on patented intellectual property.*
- *The courts should apply anti-trust laws to ensure competition in the biotechnology industry.*
- *The term of ownership of patented intellectual property should be re-examined with the goal of balancing economic returns to investment versus opening the knowledge for future productivity and innovation.*
- *While there was not unanimous support for the recommendation, many workshop participants felt that the Patent and Trademark Office should issue utility patents only on the final product (plant genotype), rather than individual components or processes (e.g., genes or transformation methods).*

Need to Identify and Involve Stakeholders in Defining the Public Good

There is a need to identify and involve stakeholders in defining the "public good" with respect to intellectual property rights, and in setting agendas and policies for public institutions.

Recommendations

- *NABC, in collaboration with land-grant and other universities, and organizations such as CAST (Council for Agricultural Science and Technology), should sponsor a national panel of stakeholders in agricultural biotechnology (farmers, consumers, environmental groups, government, seed trade associations, etc.) to define the "public good;"*

assess the effects of intellectual property rights on technology transfer and utilization; and issue a report.

- *NABC should encourage greater participation of legislators and other government officials in NABC annual meetings.*
- *For public input to have impact, the public institutions should seriously listen to comments and be held accountable to public advisory groups.*
- *Appropriate research roles for the government and public institutions include enhancing the use of biotechnology in minor crops to promote diversification for family farmers, promoting new and innovative uses of agricultural commodities through biotechnology, and promoting environmental responsibility in the use of agricultural biotechnology products. These roles can be implemented only if public funding for agricultural biotechnology research is increased.*

Research Incentives

The shift from public to private funding is influencing the direction of research programs. Support is still needed for quality research and outreach with the public good in mind, regardless of short-term potential for commercialization. The incentives for the researcher need to be considered as the funding structure and the research products change.

Recommendation

- *There should be motivation provided for fundamental and applied research, for commercialization of results from research and for exchange of information with other researchers, teachers and extension faculty.*

Reinvestment of Profits from Publicly Funded Research

Publicly funded research generates valuable intellectual property which, in turn, may generate income to public institutions.

Recommendation

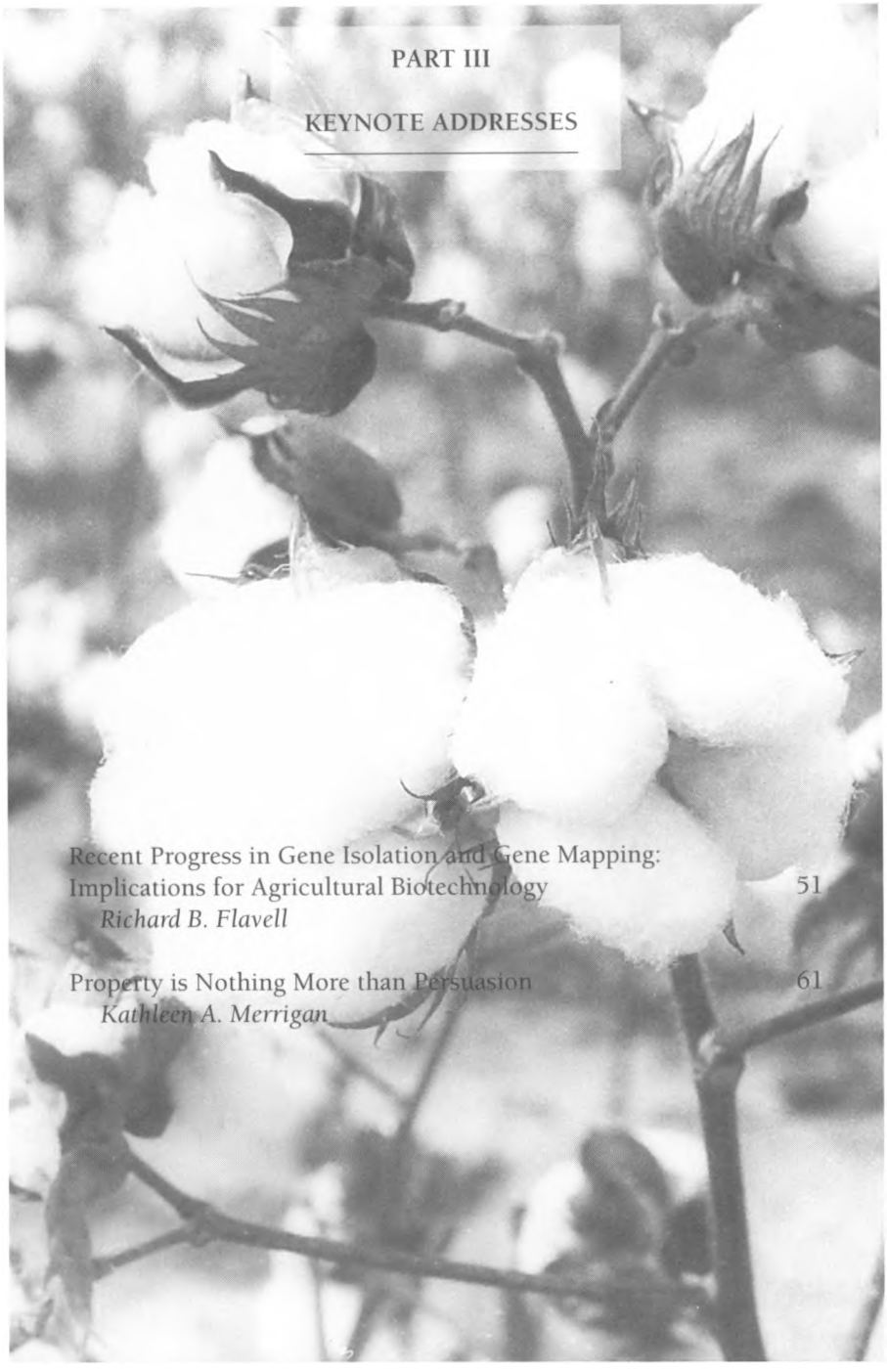
- *Distribution of royalties and license fees from publicly funded research should be returned to the institution/unit that developed the intellectual property, to be reinvested in research.*

Research Regulation and Safety

There is a need for appropriate balance between caution, innovation and commercial development in the regulation and the release of new products from biotechnology.

Recommendation

- *Products posing different levels of risk should be treated with different levels of stringency in oversight. Care in regulation is of special concern regarding environmental release of genetically modified organisms with the ability to propagate in the wild.*



PART III

KEYNOTE ADDRESSES

Recent Progress in Gene Isolation and Gene Mapping: Implications for Agricultural Biotechnology

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The improvement of plants and animals for specific purposes has been at the heart of economic prosperity and stability of societies throughout history. It remains so today for all societies, although the economic importance of domesticated crops and animals differs widely between countries. The basis of improving organisms for specific purposes is changing combinations of genes. It always has been that way and always will be, because the properties and performance of one individual of a species versus another, in a given environment, is closely related to the genetic differences between them. "Classical" plant and animal breeders have achieved major improvements by selecting parents, making crosses and selecting progeny that serve human beings much better than wild strains in domesticated agriculture. However, relatively few species have been subjected to intense artificial selection. Many improvements have been made by the incorporation of a few genes, and sometimes a relatively rare version of a single gene, into already successful plant cultivars. Most advances have resulted from recombining versions of many genes into new and better combinations.

In spite of substantial progress achieved by breeders in the past, our crops and animals still do not serve us optimally because the right genes and gene combinations have not been found. Furthermore, our needs and rural, economic and political environments keep changing. Preferences for land usage and local demands for food, fiber and feed also rarely remain constant. Thus, the objectives for breeders keep changing and changes are expected to continue.

Our crop plants and forests regularly suffer in yield and quality due to environmental stresses of flooding, drought, heat and cold. They also suffer from pests and diseases, sometimes to dramatic extents. Often, yields are sustainable only with inputs of artificial fertilizer, fungicides and insecticides that may not always be available or are considered undesirable because of their perceived effects on the environment or on human health. There is concern over undesirable linkages between human health and possible "toxins" in food. Furthermore, improvements in appearance of food, taste, cooking properties and other quality traits are continually being demanded. Improved plants and trees as raw materials for industrial processes are also needed around the world.

Improvements in all these vital characteristics can be made by utilizing genes in new ways and in new combinations. 1 would maintain it is a very high priority to continue to do so. Societies that fail to adapt crops and animals to its needs and to changing environments will certainly fail. In this short paper I highlight some of the progress and issues of plant biotechnology that are emerging from discoveries of genes and gene mapping. Plant biotechnology is emphasized because this is my own area of specialty. Nevertheless, most of the salient conclusions are relevant to farm animal biotechnology.

Gene Mapping

Gene mapping, that is the determination of the localization of genes in a genome, is now an integrated part of the process of improving the genetic constitution of organisms to serve humans better. We need gene mapping to:

Know how traits, simple or complex, are genetically determined;

Make selection of gene combinations more efficient in breeding programs;

Assess genetic diversity within a species at defined loci; and

Identify the role of isolated genes in specifying phenotypic traits.

We have vast stores of genes and variants of genes in the organisms of the earth. It is essential that we maintain good representative samples of gene variants and combinations of genes in seed and embryo banks. Plant breeders have utilized some of these genes over the centuries without, of course, knowing of their existence as chemical, functional units; as genes. Before the recent phase of molecular biology, we knew of the existence of a gene only when two individuals had different variants of the gene and the alternative form could be identified in the progeny of a sexual cross and mapped to the same chromosomal position. This was the genetics that Mendel opened up for us.

To map one gene locus on a chromosome a second identifiable gene is needed, because gene mapping involves localizing one gene with respect to another. Major problems in producing maps have been a shortage of genes easily identified from their effects on the properties of an organism and the shortage of reference, identifiable marker genes in the same individuals.

Nevertheless, in a few plant species that have been the subject of much attention by geneticists (maize and pea) genetic maps displaying many localized genes have been produced. Now, thanks to the introduction of the techniques of molecular genetics, the opportunities are very different. First, it is not necessary to have variation in the effects of a gene to identify it — it can be identified by its chemical characteristics. Second, molecular reference markers that map all over the genome are readily created for many species. These detect variation in DNA sequences that are so abundant that it usually exists in all individuals. These two advances have revolutionized the making of genetic maps.

Maps of maize, soybean, wheat, rice and pine, for example, have been created in the last few years with many hundreds or thousands of markers. It is now possible to generate a comprehensive molecular marker map from scratch in less than one year, if plants with segregating genetic variation are available. The commonly used molecular markers are:

1. Short fragments of DNA (probes) that hybridize to one or only a few sites per genome and are used to find fragments in total DNA cleaved by restriction endonucleases. Variation between individuals in endonuclease recognition sites leads to fragments of differing length (Restriction Fragment Length Polymorphism, RFLP) which are easily recognized using the DNA probe after fractionation of the DNA fragments into different size classes.
2. Fragments of DNA in one or two copies per genome that terminate in specific short sequences that are recognized in vitro by DNA primers that can initiate DNA synthesis and consequently be amplified in the polymerase chain reaction (PCR). Variations in the primer binding sequences or in the length of DNA between the primer binding sites give rise to differences in the product of the PCR.
3. Fragments of DNA recognized by a combination of: 1. and 2. above (Amplified Fragment Length Polymorphism, AFLP).

Geneticists and breeders are now in a phase of rapidly expanding genetic maps using molecular DNA markers and genes specifying easily scorable properties in the phenotype or in the test tube.

Where DNA sequence or other easily scored markers are present all over the genome it is much easier to discover the genetic components (QTLs) of genetically complex traits and map their location reasonably accurately. This opportunity is providing geneticists and breeders with the means of locating very important genes that were previously unrecognizable.

IDENTIFICATION OF GENES VIA LARGE-SCALE GENOME PROJECTS

The identification of genes and their mapping is growing by the application of DNA sequencing techniques. Gene products are being sequenced as well as the genes themselves. Messenger RNAs, present wherever genes are expressed in

cells, can readily be copied in vitro into DNA using the enzymes reverse transcriptase and DNA polymerase. The DNA copies can be amplified in bacteria, isolated and readily sequenced. Parts of such DNA copies have been sequenced from some 18,000 *Arabidopsis* and 20,000 rice genes, for example. Assuming plants contain 20,000 to 30,000 different sorts of genes, clearly most genes of these species will be characterized by sequencing in the relatively near future. Once the sequences are in databases, they can be compared with all other genes similarly sequenced in any other species. Now that the functions of so many genes and parts of genes are becoming known in bacteria, yeast, *Drosophila, C. elegans* and mammals, clues to the function of an unknown gene can be readily obtained. Thus, plant gene identification is now being aided by the molecular genetics of many species across the kingdoms — a very significant change for plant scientists.

To get a more complete understanding of a gene's function it is useful to discover if it maps on a chromosome at a site known to influence a specific character. Also, it is desirable to insert the gene into the species to inactivate the resident gene and then observe the change to the organism. This is readily done in many plant species, even though it is relatively time consuming. Alternatively, if some gene sequence is known, it is possible to screen large populations of plants to find individuals where a roving transposable element has been inserted into or near the gene of interest and see what effects the mutation, insertion (and inactivation), has on the individual.

The application of these approaches to *Arabidopsis* and rice, as representatives of the dicot and monocot groups of plants, is providing molecular markers and tools for exploring all plant genomes. These tools have greatly expanded our knowledge of genes and ways of mapping genes and ascribing functions to them.

Another approach to identifying and mapping genes is to sequence long chromosomal regions, discover the genes from the sequence, scrutinize each sequence against other known genes, and investigate the effects of mutations in the gene via experimentation or by discovering if the gene co-localizes with known mutations. An international program has been established to sequence the complete *Arabidopsis* genome (except perhaps the repetitious telomeric and entromeric regions) by 2004. A major initiative to sequence the rice genome is being undertaken by the Japanese. These major plant genome sequencing projects sit alongside programs to sequence the human genome, and those of several bacteria, yeast and *C. elegans*. Thus, in a decade or so nearly all genes in some species will have been recognized and it will be possible to investigate the role of every gene in an organism. However, there will be the need to investigate the variation within key species, the allelic variation, because improvement depends upon utilizing specific alleles. These are not necessarily easy to construct in vitro from other alleles without knowledge of the subtle links between structure and function, especially for regulatory genes.

Specific genes can be isolated from banks of clones of plant mRNAs or chromosomal sequences if a means of recognizing a specific gene in the banks is available. The bank can be screened using a DNA fragment with the same or similar sequence or an antibody against the gene product. Single gene sequences can also be amplified from mixtures of mRNA or chromosomal sequences by the polymerase chain reaction (PCR) using short DNA sequence primers known to be specific for the desired gene. Often, however, the sequence of the desired gene is unknown, if a gene is mapped relative to nearby known molecular markers, the gene can be isolated by first isolating the chromosomal DNA fragments containing the marker and then finding the neighboring fragments by sequence homology between overlapping fragments and by "walking" along overlapping fragments until the desired gene is reached and identified. This route to genes is an important reason for developing the means of mapping genes on chromosomes in fine detail.

Genes are also being isolated in maize, Antirrhinum, petunia and *Arabidopsis* following their inactivation by the insertion of a "jumping gene" into them. Purification of the jumping gene fragment from its new location leads to co-purification of the inactivated gene.

Mapping of Genes Based on Conservation of Gene Order During Evolution

Recognition of a gene in one species can help recognition of the equivalent gene in another species. This can be through similarity in sequence where this is known, but plant breeders and geneticists wish to select parents and analyze genetic variation where the varying sequences are unknown. Now, from recent knowledge of genetic maps, it is possible to predict the location of genes in one species from their location in related species. This is because the sequence and linear order of the genes along chromosomal segments are conserved during evolution. Thus, once the related chromosomal segments are identified (this is relatively easily done using conserved molecular markers) genes known on a segment of one species can be expected to occur in a similar location in the related chromosome segments of other species. This discovery is of profound significance for plant breeding and genetics. The genetics of related species can be combined into a common pool of knowledge. The genetics, physiology and biochemistry knowledge gained about one species can be used to aid the genetics and breeding of its relatives. Therefore, the knowledge of genetics, physiology and biochemistry of rice can be transferred to maize, wheat, etc., and vice versa in all combinations. This discovery will serve to unite plant genetics and plant geneticists whether studying a model species or a crop.

It is clear that genes, gene products and/or segments of genes are conserved across the kingdoms and strongly within the dicots and monocots. Thus, information and genes isolated from model species such as *Arabidopsis* or

rice are extremely useful for isolating and mapping genes and discovering the function of genes in crop plants. The case for a role for research into model species to underpin crop improvement is now proven. This gives crop improvement research a very different profile and has substantial implications for research funding bodies.

Impact of Gene Mapping on Agricultural Science

We are already witnessing the impact from the incorporation of the new gene mapping into agricultural sciences. Plant breeding companies are now able to learn which chromosome segments they have selected in successful improvements over the past decades, which segments are associated with what traits, which segments are desirable, and which carry undesirable genes. It is possible to conclude where recombination sites are localized, what genetic linkages are readily broken, and which are very difficult to break. The introduction of known desirable segments into elite cultivars by backcrossing is now achieved much more rapidly and precisely using molecular diagnostics for the segment.

As breeding companies recognize the segments they wish to preserve or substitute it will be possible to define the desired genotypes by a collection of markers. The assembly of genotypes by molecular markers will be followed by computers. The whole process of breeding could be monitored by computers with little need for field trials, especially in the early generations of genotype assembly. This approach is dependent upon markers being measured rapidly, efficiently and cheaply. Automation of such procedures is being tackled by the large breeding companies, but it has yet to be proven as cost effective throughout large breeding programs. The DNA "fingerprinting" of elite germplasm by molecular markers will lead to companies being able to recognize their specially selected gene combinations in the breeding material of other companies. Legal suits have already emerged from companies marketing the germplasm of others.

A big impact of mapping will be as part of the large program of discovery of new genes. As the determinants of key traits, including those determined by many genes, become known at the molecular level, new variants will be recognized and followed as DNA molecules, not just as chromosome segments in breeding programs. When specific genes from any organism are redesigned for use in plants and inserted into crops by transformation techniques it is possible to create variation in plants at will and evaluate it. The impact of being able to improve any attribute by adding a limitless supply of genes from the genome projects of species from all the kingdoms and their variants is going to be enormous. New ways of achieving improved plants will be devised and these plants will serve new customers, markets and industries. The possibilities will be limited by our imagination and no longer by the gene pools within the species. Agricultural science will become much richer.

The issues created by the new gene technology are very substantial and rapidly evolving. The details vary considerably from crop to crop and society to society. Therefore, the future is difficult to predict with precision. One can be certain, however, for the foreseeable future the application of gene technology to crop improvement will be a topic for debate. Many views abound on the ethics of manipulating genes, but many of them are based on scientific ignorance of the processes involved and of the past history of crop improvement. This, however, does not make the views any less important. Some people insist that they wish to know if "foreign" genes created by a scientist have been inserted into their food. They, therefore, seek to have all food with additional genes labeled as such. This creates huge problems of how to create meaningful labels and how specific variants are kept separate in distribution systems, especially in commodity crops. Food safety is a very important issue and anything that could undermine food safety carries much risk in the minds of the public. Assessment of what is healthy and safe is very expensive and long-term. The issue is made more complex by specific food constituents having adverse effects on some individuals but not others.

Conditions on how genetically manipulated foods and non-food crops will be introduced in the U.S., Europe and other countries have been agreed upon. They are probably acceptable to most citizens, but not to all. There are significant groups of people in certain societies that are hostile to the technology. These groups, aided by sections of the media, may make it difficult for supermarkets and restaurants to sell genetically engineered products. At present, retailers are cautious about marketing such products, requiring evidence of public confidence before proceeding.

A major issue that will impede international trading of genetically engineered products is the lack of harmony between legislation and licenses governing the sale of such items in different countries. There is, therefore, an urgent need for international agreements on legislation and licensing.

Plant improvement has always provoked product displacement and changes in land use, producing economic and social consequences that benefit some societies and/or individuals and harm others. The new genetics will no doubt lead to new uses of plants as raw materials that will change farming patterns. Production of novel oils in temperate crops may substitute for imports of tropical crop oils, for example. Pharmaceutical proteins could be produced in plants instead of bacteria or animal cells and novel starches could be produced in potato instead of maize.

Plant improvement will become much more complex — technically and intellectually. It will, therefore, become more expensive. Plant breeding in western countries is likely to be increasingly dominated by the multinational companies. There are concerns that this may decrease choice for farmer and consumer.

One of the major concerns of the adoption of transgenic plants is their potential effects on the environment. If foreign genes are spread via pollen into populations of wild relatives and accumulate, the natural populations could be genetically contaminated forever. In this area there are ethical as well as scientific issues. It is not easy to predict gene flow from cultivated crops to wild relatives or the ecological consequences of such gene flow. The principles are not different from the present growing of highly selected agricultural variants in places where wild relatives also grow. However, the specific outcomes may differ on a case by case basis and are not easy to predict. Plant species have always evolved by changes in gene frequency and plant breeders and agriculture has inevitably influenced ecosystems dramatically. Will the continual and ever-increasing use of novel genes designed by researchers provide disruption at too great a rate? Or will rates of change be influenced little by changing the gene pools of our crop plants?

If any environmental damages were to result from the use of novel genes who will be responsible? Who will pay? These legal issues are likely to influence the extent to which improved transgenic crops are used enthusiastically.

The use of purified genes in crop improvement is a patentable activity. This is making a major change in academic institutions and industry. It will have a major effect on how such genes and improvements are used in commerce to benefit the consumer. If patents are to be valuable then they need to be filed before publication. This means that academic institutions and industries need to recognize the value of a gene long before full information on their practical potential is available and more than 10 years before a product is likely to be realized. This scenario creates problems for academic institutions and industry.

Academic institutions have to worry about when and what to publish, when and how to interact with industry, and on what terms. Industry is challenged to make decisions about future technology that is unproven or not reduced to practice. Industries argue for exclusive licenses that can cause great problems for the academic research scientist because it may be necessary to work with other companies in the future to progress research involving the licensed materials. Many scientists and academics are concerned that with patenting of the principal sources of added-value in the cultivars of the future they will compromise their public-sector status and become increasingly motivated by monetary rewards rather than scholarship. Many inventors and academic institutions wish to see their discoveries benefiting a large community. It will be important to assess whether industries holding exclusive licenses will make arrangements with breeders worldwide to move advantages to many societies or will be very restrictive. Many people are concerned about whether patents will deny developing countries the advantages of biotechnology or whether such societies will use them avidly and risk that no legal issues of any consequence will result.

If plants, in contrast to genes, are allowed to be patented this is likely to inhibit the flow of elite germplasm around the world. Free flow of germplasm has been very important in the history of plant improvement.

It is not possible for any individual or group to predict or control all these issues. Societies must monitor the issues and develop laws and case history to ensure that the production and exploitation of gene technology realizes its potential, globally, to help the health and wealth of all societies.

Concluding Remarks

The advances in gene technology and genetic mapping are driving plant and animal improvement into a new era. It is an era that will be very exciting and productive but will also have argument, economic change and some social chaos. This is probably inevitable given the way genes and gene combinations can be recognized, redesigned and exploited as never before in the history of plant breeding. The industry will change, as will the role of research in public sector institutions underpinning the industry. There is tremendous scope for the new genetics to influence agricultural research — it has already begun — but consumer acceptability, investment needs, and laws will have a greater influence than ever before. The way forward is complex. But hopefully the needs to provide food and materials in a sustainable way will always be at the top of the agenda.

Property is Nothing More than Persuasion

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I am not persuaded that the U.S. system of intellectual property rights (IPR) makes sense, especially as it pertains to plants. I wonder: *if many people are like me and are not persuaded by our property rights, does the system really exist?* It is a bit like that age-old question: if a tree falls into the wood and no one is there to hear it, does it make a sound?

My library includes a new (1994) but already dog-eared book, *Property and Persuasion,* by Carol Rose. Rose is fascinated by the ways "people make up and change their minds about property and the strategies and arguments they use in persuading others to do the same." The book cover is a photograph of a rickety fence held up by string. Rose points out that anyone could topple the fence but because people are persuaded of the property right, the fence is respected and the property right coffered. Force and violence are signals that a property regime is faltering. Her conclusion is the underlying basis of property must be persuasion.

The Indictment

Why am I not persuaded? I could approach the patent issue many ways and raise questions. But since this is a meeting with many researchers participating, most from public universities, let me step inside your shoes and consider three facts.

Fact: *Patents influence university research agenda.* University researchers are under pressure to supplement dwindling budgets with industry-sponsored projects and pursue joint university-industry IPR efforts. Nowhere is this pressure more evident than in the field of weed science. Weed science departments receive a minimal share of university budgets since scientists are expected to raise their own funds from industry sources eager to "buy" university time to develop herbicide-tolerant crops. As a result, weed scientists have few resources to dedicate to nonchemical weed control research. Patent seeking can also

lead to unintended conflict-of-interest problems. For many years 1 served as the principal staff person dealing with bST (recombinant bovine somatotropin) in the U.S. Senate. When safety questions were raised and the Government Accounting Office (GAO) began its inquiry, it was a struggle to find a single university expert who had not, at one time or another, been on the industry dole. By the way, do include Jane Smiley's new novel *Moo* on your reading list. A central theme is the effect of industry sponsorship on land-grant university research.

Fact: *Overly broad patents stifle research.* Most researchers argued that the European Union soybean and Agracetus cotton patent awards were too broad. Researchers were also upset by the Ventor/NIH sequencing patent because of its lack of utility. These are just some better known examples of misapplied patent authority that had the potential to stifle research and development worldwide.

Fact: *Patents lead to increased research costs.* Patents carry high transaction costs and the people pocketing most of the profit are lawyers. Patents can also be viewed as research and development (R&D) taxes, with the oncogene mouse serving as a prime example. Rather than improving research conditions as advertised, the mice sell at such exorbitant prices that they have, in turn, raised the price tag of scientific inquiry throughout the system.

Since 1 am only looking at patent problems from the research vantage point, my indictment has merely scratched the surface of what will be an extensive discussion to follow. My basic point is that the U.S. IPR system has so many problems that I am not persuaded it is a system worth supporting. And 1 am not alone in this skepticism.

Problem 1: **U.S.** Citizens Are Not Persuaded

I am a member of a tiny club of people who have sat in the patent library studying plant patents. How tiny you ask? I spent a summer reviewing more than 2,000 plant patents and only once did I come across another human being. I remember the day well. I was so excited — could this be a compatriot in plant patent inquiry? No, explained the man as he pulled a box of patents from the shelf, just a guy in search of a nice rose sketch to photocopy for his mom's birthday card.

The public is hardly persuaded that our current system of IPR is a good one. Since passage of the first U.S. plant patent law more than six decades ago, the issue of plant IPR has received little public attention in this country. In a playful but instructive exchange, biotechnology watchdog Jack Doyle once said, "Nine out of ten people walking down the street do not even know you can patent a plant." To which biotechnology gadfly Steve Witt responded, "Frankly, nine out of ten don't know what a patent is!" The lack of public interest and knowledge about patenting and biotechnology is dark cloud hovering over researchers, industry and public interest groups alike.

The legislative history of plant IPR is telling. Despite its importance, plant 1PR issues have received no more than cursory attention from our policy-makers. In 1930, finally responding to the pleas of Thomas Jefferson, the U.S. Congress passed the Plant Patent Act after little debate and by voice vote. In 1967, President Lyndon Johnson appointed a commission to study the entire patent system. Ironically, just three years after the commission concluded that the patent system was not the proper vehicle for plant protection, the U.S. Congress passed the Plant Variety Protection Act following only one hour of debate. In 1980, the Supreme Court ruled in Diamond v. Chakrabarty that patents are to be allowed on all living matter. Following this decision, the U.S. Department of Agriculture (USDA) commissioned a study to evaluate the implication of the Court's ruling for agriculture. The study uncovered little relevant data and recommended that the USDA undertake additional analysis; work that has never been done.

Given the limited public debate, I was amazed at the fervor with which the Bush Administration argued for plant IPR during the Earth Summit and the Clinton Administration fought for interpretative statements to accompany the Convention on Biological Diversity. You would think that all of America was up in arms on the topic. However, the sad truth is that most Americans were oblivious to the fact that these fights took place; "our" position was defined by a few industry leaders. U.S. policymakers would be wise to review domestic laws and engender a public discussion about appropriate IPR systems before leaping onto the international scene to impose "our" answers on the rest of the world.

Problem 2: Our Southern Neighbors Are Not Persuaded

I was asked to comment on gene mapping. Richard Flavell has done so well in covering the topic (see paper, page 51) that 1 would like to turn the assignment around and ask you to think of gene mapping in a more literal way. Politically, the most interesting gene map is the map of the world produced by good old *Rand and McNally*. If we plot the worlds germplasm resources on this map we discover that most of the world's genetic wealth is concentrated in developing countries near or below the equator. This has led to what many of us refer to as the "North-South conflict." The North has wealth; the South has germplasm. Developed countries in the North recognize IPR and push for worldwide adoption of such systems. Developing countries in the South reject Northern ways and are in search of property regimes better suited to their needs.

To avoid conflict and woo the South toward Northern IPR arrangements, three "lucrative deals" have been offered in exchange for access to Southern germplasm. I think it is important to reflect upon these deals because I have come to believe, with more time and information, that even popular game show host Monty Hall could not give them away.

Behind door number one, we have the most popular deal — formal exchange between a developing country and a private company. Such a deal was struck between Costa Rica and Merck & Co., Inc., in 1992. Costa Rica agreed to provide Merck exclusive access to the country's germplasm in exchange for one million dollars and royalties on commercially viable products produced from Costa Rican sources. Many analysts, including my colleagues at the World Resources Institute, hailed this as a breakthrough and have urged developing nations to replicate this model. To me, this is neither a good nor lasting deal. First, it outraged other Latin American countries who suspect that some of their germplasm resources are closely related, if not identical, to the germplasm found in Costa Rica. Therefore, the Merck deal may hinder the ability of neighboring countries to develop their own property. Second, the deal provides no assurance that traditional knowledge and resources will be preserved. Rather, it will likely lead to the preservation of certain resources over others, thereby accelerating the loss of biodiversity. Finally, it is inconceivable to me that a country with as many riches as Costa Rica would sell out for a measly one million dollars. Maybe the moral of the story is that poor countries sell cheap. However, I anticipate trouble in paradise if Merck makes billions of dollars from Costa Rican germplasm.

Behind door number two is the deal of extending "farmers' rights" worldwide. Farmers' rights are the developing world's response to our IPR. Rather than concede to Northern IPR demands, developing countries have devised a system that recognizes the contribution of farmers to the development of improved germplasm by allowing farmers free access to protected materials. This deal is a token payment for the decades of professional breeding provided by farmers and it interferes with the nonmarket logic for maintaining biodiversity among most indigenous communities. While some Southern leaders may now argue for farmers' rights, convinced it is the best they can hope for, this deal is a cheap payoff and it fails to address fundamental equity issues.

Behind door number three is my favorite deal — a worldwide compensation fund. To remedy years of Northern harvesting of Southern germplasm and to placate any outstanding Southern ownership claims, an international fund has been established. Northern countries and industries are expected to contribute to this fund to preserve biodiversity in developing nations. I chuckle when I hear anyone assert that this fund will accumulate more than a few million dollars. Sure, industry may contribute some money, but resources are tight everywhere. Seed companies, for example, generally operate at a five percent profit margin and biotechnology companies remain long-term investments. In Washington, Congress is cutting budgets left and right. Where will the money for this fund come from? The conclusion I draw is that this deal is nothing more than an empty promise.

It is only a matter of time before Southern leaders recognize that these deals are not worth the trade of their germplasm. Unless persuaded otherwise, it is

unlikely that Southern leaders will go out of their way to enforce current deals that primarily benefit transnational corporations. Actually, if I was a Southern leader, I would argue that countries in the South should band together and close off borders to Northern plant prospectors. A germplasm embargo, modeled after the successful Ethiopian embargo on coffee, would bring the North back to the bargaining table and give the South more time to develop its own property protection strategies.

The world would be well served if the South sorted out its position on IPR sooner rather than later. That way we would all know where we stand. To encourage this, 1 suggest two actions. First, Southern nations need to hold a series of intensive meetings to address plant IPR issues and to develop alliances between Southern countries. Second, additional leadership is needed from non-governmental organizations (NGOs) on this topic. For example, I can count on one hand the number of U.S.-based NGOs with sufficient expertise to engage in the plant IPR debate. The foundation community would provide a great service by funding NGO staff hires for IPR and supporting an international IPR summit for environmental, rural advocacy, progressive farm, and biodiversity NGOs.

Problem 3: The Experts Are Not Persuaded

I like nothing better than a good book. 1 sometimes rush through, wanting desperately to know how the story ends. Once in a while I am disappointed. Maybe you have had this experience. You read hundreds of pages anticipating a grand ending, but the author seems to run out of steam at the last minute, leaving the reader a hurried, unsatisfactory conclusion.

This experience happened to me a couple years back in reading the National Academy of Science (NAS) report, *Global Dimensions of Intellectual Property Rights in Science and Technology.* After years of study and almost 400 pages of analysis, the book "concluded" with a list of issues for future research. Described by the authors as a "coda" to the main body of the report, they raised questions at the very heart of the biodiversity struggle. For example, the authors wonder the extent to which IPR can have detrimental consequences for innovation. They also worry that few have really studied the effect of high levels of IPR on the economies of developing countries. The NAS study team suggests closer scrutiny of the non-Western styles of property protection:

> The introduction of IPRs throughout the world has involved propagating as broadly as possible a Western cultural view of the concepts of owner-ship and rights. Some non-Western countries have voluntarily adopted Western-style IPR laws in the process of modernization. Western countries cannot necessarily count on a continuation of this pattern of adoption.... Other cultures and legal traditions, including those in Asia and throughout the Islamic world, may have different concepts of optimal ways to encourage creative participation in society. These alternative cultural traditions and practices must be better understood in building a new global IPR paradigm.

It seems that after all their work, even the experts at the Academy are not persuaded that our system is the right one. My role is to raise questions — to provide a counterpoint to help stimulate our discussions during the next two days. I begin by issuing a challenge — let us leave Friday, not with a handful of good questions that will be shelved or compiled in a coda, but with action plans!

Let me give you an example of a specific action plan that appeals to me. While the emerging common property resource literature has exposed some diversity in existing property management schemes, I think that it is only a small beginning of the needed scholastic effort. My action plan would be to set up a Global IPR Dialogue. Foundations, universities, the NAS and other nonpartisan scientific institutions would pool resources to organize and fund a dialogue among scholars. The Dialogue would bring together 100 "Fellows" — individuals who are creative idea-generators. Geographic diversity is important and half of the Fellows would hail from developing countries to enrich the Dialogue with nonwestern IPR perspectives. The Dialogue would last three years, with much of it taking place over the Internet. However, Fellows would meet in six seminars to provide an opportunity for group exchange. Selected resource people from a variety of disciplines and professions would participate. The location of each seminar would be carefully chosen to fit the issues discussed. For example, resource conservation issues might be considered in Brazil where the riches of the Amazon are under dispute. Western patent law might be discussed in Washington, D.C., where direct access to the U.S. patent and agricultural libraries is available. Fellows would receive general research support during the three-year period and travel expenses to attend Dialogue seminars. In exchange for this support, Fellows would be responsible for rigorous reading and writing assignments, public presentations in their home countries, team-research projects with other Fellows, and publication of a final paper in an edited volume produced and distributed by the Dialogue.

At the very least the Dialogue would help bring attention to IPR issues, expose non-Western systems of IPR to greater scrutiny, and encourage more scholars to enter the field. At best, the Dialogue would begin to answer the questions raised by the NAS coda.

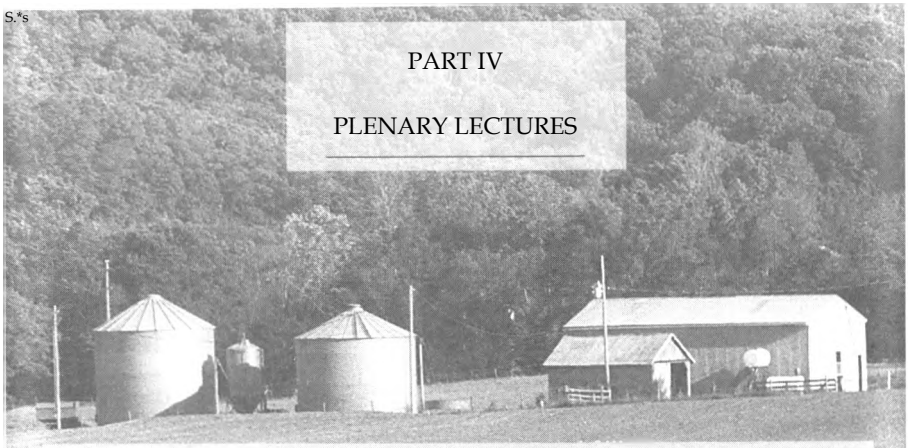
That is my attempt at an action plan. What is yours?

Confronting **QWERTY**

To conclude my recommendations for summer reading, I suggest Paul Krugman's new book — *Peddling Prosperity: Economic Sense and Nonsense in the Age of Diminished Expectations.* Krugman reflects back to a paper by Paul David and Brian Arther of Stanford in which they introduce the idea of QWERTY. Krugman describes QWERTY as "the economics of getting locked in" and defines it as aversion to change. It sounds like an odd word, but we have all stared at QWERTY a thousand times . . . QWERTY spells out the letters on

the top left row of the typewriter keyboard. When the typewriter was first developed, the letters were arranged deliberately to slow people's typing to avoid jamming the machine. Today however, machines can go much faster and yet people refuse to throw out the old keyboard and learn better ways.

1 conclude with QWERTY because I think we are stuck with an 1PR system that does not meet today's needs. We need to radically change how we think about property. Until we are all persuaded that we have it right, our system is precarious at best.



PART IV

PLENARY LECTURES

Access to Intellectual Property in Biotechnology: Constraints on the Research Enterprise

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Intellectual property rights (IPR) in biotechnology are having a dramatic negative effect on the progress of nonprofit research. Although patent policy and law intend to facilitate research progress, the current practice has led to many barriers in access and use of genetic materials and DNA technology. Such barriers restrict the free exchange of information and threaten the health of our nation's scientific enterprise. Policies related to patents and licensing are increasing the cost of research at a time when funds for research are being reduced.

We wish to discuss some current issues related to research in biotechnology carried out in academic institutions, particularly land-grant universities, and the rapidly changing roles of scientists in relation to intellectual property and industry. The rapid changes in the arena of intellectual property are more acute in the area of biotechnology, which is still in the early stages of development and where many issues are not yet well defined. Further consideration is needed of the costs and benefits of current patent policy and law. Problematic examples are discussed. Some provision (amendment or extension of law) should be made to foster the conduct of basic research in universities and other nonprofit research institutions, and to some extent provide an exemption from the law that governs commercial research and development.

Biotechnology and the Land-Grant Universities

Life is not simple for an academic institution engaged in biotechnology research today. As land-grant universities attempt to redefine their mission relative to society, conflicts arise over the interrelated roles of research and protection of

intellectual property. Even as intellectual property rights are pursued more vigorously by universities, the heart of the research enterprise is being constrained by the protection of intellectual property owned by others. Industry can invest much more in obtaining and defending intellectual property than universities can. As the law stands, and as current policies are enforced, it is unlikely that the balance will tilt in favor of the universities.

In the last two decades, universities have redefined their approach to technology transfer. The universities have simultaneously viewed it as a channel for added revenue and as a vehicle for ensuring that the discoveries of the laboratory are transformed into goods and services beneficial to society. Aggressive businesslike pursuit of protection for intellectual property generated at a university (which can then be licensed to a company for development) has led to the erosion of an apparent special status for universities as the home of exclusively "philosophical" activities. With this change, university efforts actually receive no "research exemption" and university faculty have no special right to explore patented inventions or to utilize protected findings or technologies.

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 wellbeing of our citizens. It is of particular concern when the research is carried out with federal funds and the cost of the research is either greatly increased, or it becomes impossible to carry out the research at all.

The traditional relationship of scientists and their funding agencies has changed. Since the Bayh-Dole Act of 1980, funding agencies have allowed intellectual property to be owned by the institution where the research was conducted. Generally, universities will retain ownership of patents even if the majority of the funding for a specific project comes from outside sources. Industry-funded research at universities usually requires some specific industry rights to licensing that ensures some potential or expressed degree of access to intellectual property resulting from the research. If a company obtains exclusive rights to license, they can have a great deal of control over subsequent technology based upon the patents. In many cases, related projects conducted by the same scientist are derived from public funding, often confounding the issue of who owns what.

Issues of Ownership

Under appropriate conditions, the sequence of nucleotides that represents a gene may be patented. The patenting of genes must still satisfy criteria of novelty, utility and reduction to practice. Anonymous gene sequences with no knowledge of function are not sufficient for patent protection. It is not yet resolved to what extent similar sequences are covered by specific gene patents. If a gene for a specific enzyme was patented, should that patent cover all genes

encoding that function or only that specific sequence? Much of the variation between related genes for the same function could be significant and valuable. What if the gene was obtained from a related member of the same species that had a different sequence? What if the gene was from a distantly related species? Some principles of what constitutes "equivalence" for a particular gene remain to be resolved. The issue of equivalence is important because once a sequence of a gene of known function is made available through publication or through a public database. It is possible for a molecular biologist to obtain an equivalent gene from another individual of the same species or of a different species. The different species could be as distantly related as a plant and an animal.

Issues of ownership of genes have become more critical as more large-scale sequencing projects are carried out to identify genes from organisms for commercial application. Specific genes with potential application can then be patented which means that use of these genes could be removed from the public domain, and research into their potential applications could be curtailed.

It is common practice to use patents and licensing to protect some genes where commercial development is possible. Current procedures for obtaining use of licensed genes can be extremely cumbersome and expensive. In fact, negotiating agreements that allow universities to conduct research with genes owned by industry can delay research for years. Such delays are unreasonable when research objectives are noncommercial and are supported by federal funds. Similar situations arise for other DNA sequences used as promoters or vectors for transformation. In the past, constructs have been available with restrictions on distribution and potential commercial application, but without cost. This situation appears to be changing, and charges are being added to such agreements. A new promoter, highly expressed in plant cells, has recently been made available through a licensing agreement to individual university laboratories for $1500.

As individual genes have been patented, the question of patentability may be raised about genomic maps. The process of constructing gene maps is derived from genetic studies conducted before 1920, and is fundamentally unchanged, except for the new kinds of molecular markers and the computer software that greatly facilitates map construction. We know of no examples of the patenting of an entire genomic map. However, specific genetic markers on genomic maps have patent potential for specific purposes such as diagnosis. These genetic markers would also have utility for disease detection in humans, and in breeding of plants and animals. Once a specific marker is located that would predict resistance to a disease, for example, it would be relatively easy for a mapper to identify other markers that would be equivalent in their ability to predict resistance, but would bear no relationship to the original marker in sequence, only in genome location and linked to an allele of specific interest. It remains to be resolved to what extent markers can be protected by patent, and whether such protection might extend to adjacent regions of the genome.

A related issue to genomic mapping is the sequencing of entire genomes of specific organisms. The first entire sequence of a free living organism, the bacterium, *Haemophilus influenzae* Rd., has recently been completed. Such information could have industrial applications. However, the extent and utility of patentable information from genomic sequencing remains to be defined.

Genomic Mapping using PCR

New polymerase chain reaction (PCR)-based genomic marker technology (discussed below) has revolutionized genetic analysis for many species of plants and animals. This use of PCR was unanticipated. It represented a new application of PCR on a very much larger scale for individual laboratories than had been anticipated. Licensing of PCR has dramatically increased the cost of genomic mapping. The costs of licensing for this type of genetic analysis raise the cost of each reaction from several cents to about 30 cents a reaction. A typical mapping experiment can require tens of thousands of reactions, and a large experiment may involve a million reactions. Experiments that would have cost hundreds of dollars for materials instead now costs many thousands due to the licensing strategy for PCR. These greatly increased costs result from the patented process of PCR, and from the unusual status of the enzyme, Taq polymerase, used for the PCR reactions.

Taq polymerase has an unusual status as a reagent for molecular biology because its purchase from an approved source confers a license to practice PCR. As a result of this licensing strategy, the costs have placed an unanticipated burden upon laboratories exploring the large scale use of PCR for genomic mapping and genomic sequencing.

Taq polymerase is a heat-stable DNA polymerase purified from the thermophilic bacterium *Thermus aquaticus.* A process patent on PCR and the use of a natural enzyme for this process, Taq polymerase, (US Patent Nos. 4,889,818 and 5,079,352) have been licensed to the research community by the holders of the patents (Hoffman-La Roche Co.) through the purchase of the enzyme from specific suppliers (licensed by Hoffman-La Roche), and through the purchase of equipment and accessories from The Perkin-Elmer Corporation. The worldwide research community is considered to be an important market for the licensing of the PCR process and for the sale of the enzyme. As a result of the patenting, licensing and pricing strategy, the cost of the enzyme is far more expensive than most other widely used, easily purified enzymes of nucleic acid metabolism, such as restriction enzymes.

Of the hundreds of enzymes used as reagents in molecular biology, few are restricted through their use in a patented process. Taq polymerase cannot be purified legally by individual investigators for use with PCR. Scientists who wish to practice PCR are required to purchase the enzyme and are prohibited from purifying the enzyme for their own use. The purification of the enzyme is relatively easy and would provide the enzyme at a fraction of the current commercial price.

RAPD Markers

Randomly Amplified Polymorphic DNA (RAPD) markers, developed by DuPont Co. scientists and almost simultaneously at the California Institute of Biological Research in San Diego, provided a novel DNA marker technology for genomic mapping in plants and animals. The method was advantageous because it could be applied with no prior information and could be done using small amounts of DNA. The method was particularly useful for species with no history of genetic analysis or DNA sequencing. The cost of Taq polymerase has been the major barrier to the application of this technology to a number of new problems, for example, a large site adaptation study planned for loblolly pine that would require 1.5 million PCR reactions, making the research too expensive to undertake.

Recently, a new patent has been issued to DuPont that covers the use of RAPD markers. DuPont has licensed exclusive rights to the use of this marker technique for certain species to an Australian company, ForBio Ltd., which will license RAPD markers to individual laboratories at a specific charge for each RAPD reaction. RAPD reactions also use PCR and require licensed use of Taq polymerase. However, ForBio and DuPont have decided not to charge fees for research carried out in universities or government laboratories that "has no commercial purpose." This distinction deserves consideration; it could set a precedent for protecting freedom of inquiry.

Alternative Marker Technologies

The high cost of licensing both PCR and RAPD technology has stimulated interest in alternative methods. Several such methods are available, each with different advantages and disadvantages. These include microsatellites, amplified fragment length polymorphism (AFLP) or use of cDNA-amplified polymorphisms (CAPs) and others. All require PCR, except for the earlier methods of restriction fragment polymorphism (RFLP). RFLP methods are not well suited to large-scale experiments.

Unintended Negative Effects

For most if not all enzymes used in routine research in molecular biology, the cost of obtaining the enzyme from commercial sources is advantageous relative to the cost of producing enzyme in a research laboratory. The relative cost of production and the price of the product results in reasonable profit to the producers and savings in time to the purchasers. There is no incentive for infringement. The current circumstances surrounding the use and production of Taq polymerase are different. At a cost of a few thousand dollars, laboratories working on a small scale could, in short time, easily produce for their own research use what would cost millions of dollars through the current PCR/Taq polymerase licensing strategy. The ability to produce their own enzyme would allow some laboratories to conduct research that is essentially not affordable under current licensing requirements. Thus, the current environment could

foster deliberate patent infringement to the detriment of both the patent system and the university research enterprise.

Advances in mapping technology based on PCR raise several issues that epitomize problems affecting the current national research effort and the future of publicly funded university-based research. There is no doubt that the invention of specific amplification of DNA through PCR has been one of the most significant new techniques in biotechnology. Current strategies of intellectual property protection and commercialization may impede or block research efforts, exacting a social cost. Proprietary constraints on the practice of PCR have three aspects: the practice of the invention, the specific enzyme used to practice the invention, and the equipment needed to practice. The patent holders have chosen to license the practice of PCR through the sale of enzyme and sale of equipment that can be used to practice PCR. In part because the large-scale application to mapping was unanticipated, the licensing strategy has had unintended negative effects on U.S. research, and related research worldwide.

Biotechnology arose from several decades of research based upon the free exchange of information and materials. Most research during these crucial formative years was "basic" and was supported by public funds or foundations. Little consideration was given to intellectual property, and new information was released and made available through publication or conferences. If many of the fundamental advances made during this time had been patented, it is unlikely that the field of biotechnology would have developed by this time. It is instructive to consider how the past 45 years of progress would have been constrained if each major discovery or new process was patented and licensed. Essentially no restrictions or licensing costs were placed on any processes or molecules involved in biosynthesis, in vitro synthetic processes, methods of purification, or products of these processes. These fundamentally important advances remain unconstrained today. The free exchange of information depended upon public funding, and a certain "culture" promoting free exchange in the conduct of research.

If a major shift occurs from public funding to industrial funding, and if current intellectual property protection strategies continue to be pursued, the nature of the university research enterprise related to biotechnology could change in dramatic ways. Industrial research is more likely to remain short-term in perspective and will focus upon practical applications and products for development rather than discoveries of general interest. Industry-driven research is more likely to be directed to produce patents rather than publications. Academic objectives of scholarly work are different from that of patents in purpose and standards of proof. One of the challenges to universities is the need to maintain the high standards of scholarship while pursuing patentable technology.

What is the Cost of Research Not Done ?

The value of university research lies in the addition to the knowledge base of our society. New information and resultant technology drive economic development, maintains a competitive advantage for the nation as a whole and leads to a better informed and more productive citizenry. If wisely applied, such information should provide a basis for the conservation of natural resources and the ability to extend a higher living standard to our citizens and others throughout the world. Thus, there is an assumption that the benefits of research have high value. Yet, the inability to quantify such benefits and to predict when, how, and specifically to whom the benefits accrue means that benefits may pale in comparison to the extremely visible and quantifiably high costs of doing research. However, if another nation has invested in research and as a result has a major technical and competitive advantage, the costs of research not done become large and obvious. Currently, intellectual property protection strategies have inadequately accounted for the value of basic research.

The success, not only of our research enterprise per se, but also of our improvement of quality of life, has stemmed in large part from the traditional, unfettered pursuit of basic knowledge that has been the hallmark of our universities. With the decline in public spending and the increasing focus of the private sector upon short-term results, we are in danger of failing to build the foundation for discoveries in the long term. The problem is exacerbated by the constraints placed upon academic researchers by current interpretations of intellectual property protection. When we restrict the ability of the not-for-profit research community to take findings and push them to new discoveries and when we create costs of doing research that are prohibitive, we hinder the innovation that has served this country well — innovation that we need more than ever before.

Need for a Research Exemption for Not-for-Profit Research

In recent years, university professors have been surprised to find themselves restricted by copyright and patent laws that had not been defined or enforced in past decades. In practice, university researchers have often assumed that they could operate under a research exemption, not subject to the same constraints as industry, because they were supported by public funds and worked for not-for-profit or state-supported institutions. Recent rulings, however, have made it clear that these assumptions were not correct. Universities are subject to many of the same restrictions as any industrial organization. In contrast to the currently held belief of most university faculty, there is no general research exemption for university-based 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. It is 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. A different basis for exemption based on the sovereign rights of the states and their agency to enjoy immunity from patent infringement, has been ended by an amendment of the Copyright Act of 1990 that put the states on the same footing as other defendants. The federal government, however, has not lost these rights of sovereignty and could expand the scope of an exemption. Federal employees and recipients of federal grants could be considered agents of the government for such purposes, thus effectively receiving an exemption for government-sponsored research.

In conclusion, there is a need to modify patent policy or law in order to encourage basic research. The current status of the law and its interpretation is unnecessarily restrictive and impedes innovation and discovery. Even though universities will continue to play a role in discovering information that will be useful to industry, publicly funded basic research should still be distinguished from corporate research for profit. It is important that our current intellectual resources, the envy of the world, be fostered and maintained for future commercial development and for the well-being of our citizens.

The Impact of Patents on Plant Breeding Using Biotechnology

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My first job after graduation was breeding tomato plants for resistance to a fungus disease. It was a simple program that involved the introduction of dominant genes for resistance, from other cultivars and from wild relatives, in a backcrossing program that employed several widely grown cultivars as recurrent parents. The first lines from this program appeared to be so promising that 1 sent them to some greenhouse tomato growers for small trials. The growers agreed that they were resistant to disease but said they were also resistant to yield. This taught me the important lesson — that no matter what new gene a crop cultivar may contain, unless its genetic background supports good agronomic performance it will be of no practical interest to growers and farmers. For this reason, a major part of the application of biotechnology to plant breeding has been the field trials to prove the agronomic qualities of newly engineered forms.

Field Trial — A Guide to What is Happening

Goy and Duesing (1995) reported a survey of field trials over the period 1986-1993. During this time, they examined records of some 1,025 field trials in 32 countries. Table 1 (on page 80), adapted from their paper, shows the range of characters introduced into the five most widely tested crops. The tobacco field trials for the most part reflect its use as an easily transformed crop plant model. Although the first field trials were carried out largely by the private sector, the first in the UK was a trial of a potato transformant carrying the gus marker gene. That trial was carried out in 1986 at the Plant Breeding Institute (PBI) in Cambridge. By 1993, the private sector was responsible for 71 percent of all trials, although by then a total of 61 public institutions and 88 companies had submitted applications or notifications to the various regulatory organizations controlling field tests of genetically manipulated plants (Goy and Duesing 1995).

Table 1. Number of Field Trials and Traits Tested

TRAIT	*Potato*	*Canola*	*Tobacco*	*Corn*	*Tomato*
Herbicide resistance	16 (5)	94 (7)	29 (6)	54 (3)	21 (5)
Quality	31 (9)	57 (5)	13 (4)	15 (2)	39 (3)
Virus resistance	60 (12)	2 (2)	24 (7)	10 (4)	20 (9)
Insect resistance	34 (4)	3 (3)	19 (3)	24 (2)	16 (1)
Marker gene	23 (7)	17 (5)	28 (9)	8 (4)	4 (3)
Fungal resistance	9 (7)	5 (4)	9 (4)	2 (1)	
Multiple traits	8 (7)	2 (1)	4 (3)	0	
Bacterial resistance	9 (3)	1 (1)	0	0	
Not specified	3	1	5	5	3
Total	193	181	128	120	105

Data are from 1986 to 1993 Adapted from Goy & Duesing 1995
71 percent of trials are by the private sector

Private and Public Plant Breeding

Throughout the last 50 years some major changes have affected the way varieties are released and how breeders are compensated for their work. Plant variety rights legislation is now common in many countries and protects the originators of new cultivars against theft and illegal sales of seeds and planting stocks by unauthorized propagators. In Europe, the introduction of these schemes spawned the development of the plant breeding industry by making investment in the technology profitable through the return of royalties on seed sales. As the private sector grew in strength and capability, there was a steady trend away from reliance on public sector plant breeders to produce new cultivars of the major agronomic crops. In the UK this culminated in the privatization of the Plant Breeding Institute in 1987, leaving only remnants of the public sector breeding that had largely supported British agriculture over the period from 1910 to the seventies. Although traumatic for those who lived through the transition, it re-emphasized the important role of the public sector in basic research. However, the demise of the PBI did destroy a unique and very successful organization that directly coupled basic and applied science for crop plant improvement.

In the U.S. there was a similar, if less dramatic, trend towards a reduced reliance on land-grant university and federal breeding programs. Some exceptions include crops, such as oats and alfalfa, which the private sector regarded as too small, in terms of seed sales, to be profitable. For corn, exclusive ownership of the inbred lines needed to make up Fj hybrids provided an alternative to plant variety rights.

Patents

Although plant variety rights provided reasonable protection for conventionally bred varieties, the scheme could not protect the hard won fruits of biotechnology. The capital and personnel investments in molecular biology were considerable. These costs, and the precedents from earlier decisions for patenting living organisms, made it clear that utility patents were the answer. As a result, there has been a tremendous increase in the filing of patents to protect discoveries such as cloned genes, methods of effecting transformation, and the development of systems for using molecular mapping as an aid to selection. At Rutgers, this is reflected in the appointment of additional staff to the University Office of Corporate Liaison and Technology Transfer, which has six people who assist faculty and graduate students in patent filing. The total number of faculty at Rutgers is about 1,100. However, in one U.S. private university that evidently has great expectations of continuing to benefit from licensing fees and royalty income, the number of staff with this function is now approximately one per ten faculty members.

To illustrate my concerns and the practical problems caused by patents, let me review a situation that we now face at Rutgers and which 1 am sure is paralleled elsewhere. A most successful plant breeding program at Cook College is a turfgrass-breeding program led by Reed Funk. This program has been responsible for a number of leading varieties that are widely grown in North America. In the course of developing a transformation method for one of the turf grass species — *Agrostis palustris* or creeping bentgrass — we made use of the *bar* gene for resistance to the herbicide bialaphos (Hartman et al. 1994). The *bar* gene is widely available for research use but two patents cover commercial use, as a selective marker in the laboratory, for recovering products of transformation, or for field use to confer herbicide resistance. We have also worked with several other herbicide resistance genes that have been introduced into the same grass species. Following greenhouse and field trials, we had expected to begin discussions with the owners or licensees of these patented genes to explore how the most promising lines we had selected might find their way into the hands of commercial grass breeders. During the course of several years of meetings, correspondence and telephone calls, we have encountered a number of problems that have made this a far from easy task. Among the problems were the following. The patent owners:

1. Have other plans for the use of the gene in more important crops.
2. Fear that herbicide-resistant creeping bentgrass, a species commonly used on golf course greens, might escape as a weed and invalidate the use of these herbicides on other more important crops.
3. Are concerned that horizontal spread of the genes, by cross-hybridization with other native *Agrostis spp.* that are weeds, could more seriously compromise the use of these genes and their relevant herbicides in combination.

4. Some of the owners are concerned about development, and other costs, to obtain a registration label authorizing the use of their herbicide on a new crop species.
5. In other cases, research agreements prevent us from publicly acknowledging that we have certain genes and are working with them and may even prevent publication of our findings.

The first is clearly beyond our control. The second we naively thought would be resolved by the lack of any record in the literature that *A. palustris* is a weed species. It has been recorded as a weed in Kentucky bluegrass lawns but the absence of any reports that it is not a weed of field crops seems to be of little comfort. The third has been in part addressed by hybridization studies carried out by breeders to introduce new genetic variation into creeping bentgrass. The fourth question is a legitimate concern. Although bentgrass is not part of the human food chain, the environmental impact of increased herbicide use on golf course greens and eventually on lawns must be considered even though the newer herbicides we work with are environmentally benign. They are used at low doses, are rapidly biodegraded in the soil, and have very low mammalian toxicides.

Even when a public sector unit isolates and clones its own genes, which it may well decide to patent, there are still other problems. I am grateful to Ken Barton of Agracetus, Inc., for the following example. A new genetically engineered cultivar arising from work of this kind has to take account of additional patents and protection as follows:

1. The Cohen-Boyer patent for cloning DNA in a plasmid in *E.coli,* even though it only has several years left to run, underpins the technology of recombinant DNA.
2. The method of transformation is also subject to patent protection: For example, the gene gun is covered by the Sanford & Wolf patent (for grasses and ornamentals) whereas the DuPont Co. has patent rights for other plant species.
3. The plant material to be transformed may be covered by patents. For example an Agracetus patent, that is presently being disputed, gives the company rights to all transformed cotton cultivars no matter how they are produced. If a named crop cultivar is used, and the new cultivar is essentially similar except for the new gene, the owner of the original cultivar has rights that must be respected.
4. 1 have already discussed the question of ownership of the gene, or genes, that give a genetically engineered cultivar its new features. Nearly all single gene traits that have been cloned are protected. However, other genes may be required that are owned by other parties. For example, markers such as kanamycin resistance, the glucuronidase gene (gus)

and herbicide resistance may be needed. In order to ensure maximal expression at the appropriate stage of plant development, the introduced genes must be controlled by elements such as the CaMV 35s promoter, an organ or tissue specific promoter, or be used with an expression enhancer such as the omega sequence from tobacco mosaic virus (TMV).

Each interested party, or patentee, has to agree to the proposed use of their materials under license. Each will expect either an up-front fee, or a share of royalty income, which have to be negotiated individually. Small wonder that public sector programs with limited resources and experience in negotiating licensing fees are finding it increasingly difficult to compete with large companies who are patent holders, and thus have bargaining chips to use in negotiating deals with each other. In theory, the patent system is supposed to make material available for further research by protecting the interests of the patent holder. In practice, the patent holder can find many ways to block distribution of the patented materials and to limit the uses made of it.

Are patents as useful as publications for evaluating faculty for tenure and promotion? Probably not, but they are unlikely to hurt an academic candidate and could be regarded as an indicator of his or her awareness of the relevance of their work. Patents are, of course, much more important in industry. Judging the quality of awarded patents is much more difficult. Patents are examined by patent office specialists. They are not peer reviewed, and their treatment is entirely different to that given journal articles or grant proposals.

Are Present Intellectual Property Laws a Barrier to Exchange and Access ?

In my view, these laws restrict meaningful access to genetic information. Before patent protection is filed for, the investigators are unable to describe their work to others for fear of invalidating their patent claims. Even after the patent is filed and granted, access to the material can be denied by failure to answer requests. Such access as may be granted may not be meaningful since profitable use of the materials may be prohibited and, even if allowed, is subject to restrictions. The result is that the laws sometimes limit, or even prevent, beneficial applications. This is the cost of protecting private sector investment in plant improvement. Without it, private plant breeding would not have flourished.

What of the trend among universities to patent and protect information gained with taxpayer support? Although some have been critical, many believe that universities should benefit from the income accruing to such protection. They believe that it will reduce the tax burden, enhance facilities for teaching and research, reward and encourage faculty inventors, and create wealth and jobs for the community. However, these incentives can distract university faculty from teaching, research and more traditional forms of service to the

community. There is the danger that they may become more concerned with raising capital, establishing and managing external development or manufacturing facilities, and lining their own pockets. Negotiating contracts, licenses and royalties has now become so complex that research universities must employ specialists in these areas to protect their interests and maximize returns. A senior faculty committee at Rutgers recently spent much time in revising its scheme for dividing the spoils from royalty income between the university central administration and the deans, department chairs and researchers themselves.

Present Day Role of Public Sector Breeding Programs

Some years ago the late William Brown of Pioneer Hy-Bred International, Inc., was concerned about the reduction in plant breeding in U.S. land-grant colleges. He was worried by the prospect that the private sector would be unable to recruit young men and women trained in the technology. During several annual seminars organized by Pioneer Hi-Bred in the 1970s that brought together public and private scientists, it became clear that training in plant breeding would increasingly become the province of private sector breeding companies. Their new recruits would have had training over a broader range of subjects than before. This would include not only the traditional subjects such as genetics, plant physiology, agronomy and statistics, but also molecular biology, biotechnology, biochemistry and cell biology. Much like engineering trainees, they would learn the idiosyncrasies of individual crops, the practice of selection and the management of trials in company plots and fields. I believe that this is working well. I am less optimistic about the technology transfer of the products of long term basic research in plant molecular biology carried on in our universities. The separation between basic research and the technologies that need it and can make best use of it means that they are uncoupled in our universities. The problems and pitfalls involved in patenting exacerbate this situation. Even producing new breeding lines for release to commercial breeders is no longer simple.

I will finish by reviewing my own experience in the UK. In a sense it represented for me the culmination of the introduction of Plant Variety Rights. I joined the Plant Breeding Institute in Cambridge in 1979. At the time its varieties dominated or were prominent on the UK national recommended lists for winter wheat, spring barley, potatoes, marrowstem kale, and oilseed rape (canola). The National Seed Development Organization (a state organization) distributed these, and other products of public plant breeding, collected the royalties and passed them on to the Treasury. By the early 1980s the PBI's share of these royalties exceeded its annual

grant-in-aid from the state. Some of the UK private sector breeders resented the success of "Her Majesty's Plant Breeders" who were supported in part by the taxes they paid on their profits. Unlike the system in The Netherlands, where state breeders offered the private sector advanced breeding materials and were prevented by law from releasing finished varieties, the PBI breeders' best materials went right through to the ultimate test — the farm and the marketplace. The competition between state and private breeders, although not on an equal footing, was good for the British farmer. For example, there had been a steady increase in the proportion of homegrown wheat in breadmaking grists brought about by systematic breeding for breadmaking quality coupled with high yield. The end came when the government realized that the generation of royalty income was a salable asset and the PBI was privatized in 1987. In my view, the most damaging result was the uncoupling of theory (genetics, plant molecular biology and plant pathology) and practice that resulted. The dialogue between breeders and others at PBI was at times difficult and unrewarding, but in the long run was responsible for the achievements made over 75 years.

If we are to benefit from current technologies, that were pipe dreams 15 years ago, we must facilitate and enhance the coupling between discovery and its broad use. Where intellectual property rights and agreements hinder this we must strive to find ways to make things work fairly and efficiently.

References

Goy, P.A. and J.H. Duesing. 1995. From pots to plots: genetically modified plants on trial. *Bio/Technology.* 13:454-458

Hartman, C.L., L. Lee, PR. Day, and N.E. Turner. 1994. Herbicide resistant turfgrass *(Agrostis palustris* Huds.) by biolistic transformation. *Bio/Technology.* 12: 919-923

The Role of Intellectual Property Rights in Modem Production Agriculture

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The term "modern production agriculture" requires constant redefining because our food and fiber system continues to develop and change. Raymond Goldberg, head of the Agribusiness Program at the Harvard School of Business Administration, describes four factors that characterize the ongoing industrialization of agriculture:

> The consolidation of firms at every stage of the food chain;
>
> The coordination of the food system through long-term legal relationships;
>
> The biotechnology revolution; and
>
> The information revolution (Goldberg 1993).

These factors are contributing to the development of new, end-use oriented marketing systems that run alongside or, in other cases, displace traditional commodity systems. One such end-use oriented system is for products that derive from what are commonly known as "end-use tailored" or "identity-preserved" varieties. These varieties carry distinct traits that are preserved from the time of production through marketing to processing and consumption.[1]

Trying to describe identity-preserved systems in a single sentence, I came up with: *The global coordination of research, development, production, processing and marketing of new animal breeds and plant varieties with special traits that fill a particular producer, processor or consumer need and which are protected by intellectual property rights.*

[1] Identity-preserved also refers to products produced according to a particular process, such as according to organic standards

Biotechnology and Identity-Preserved Systems

The life sciences, particularly biotechnology, will play a central role in the development of identity-preserved systems. Advances in physiology and classical and molecular genetics allow for the isolation, characterization and transfer of valuable traits. More generally, the majority of future productivity gains are expected to come from improved crop and livestock genetics.

Robert Fraley of Monsanto Company spoke at NABC 6 on the new products and industries that plant biotechnology will spawn (Fraley 1994). Many, if not all, of the new products for improved pest, disease and nutrient management; food processing; nutritional profiles; chemicals and polymers; and biofuels will be identity-preserved.

The technology behind identity-preserved systems will be consumer driven, not just in terms of the products, but in terms of the processes by which they are made. Speaking at NABC 6, R. James Cook, Chief Scientist at the United States Department of Agriculture's National Research Initiative Competitive Grants Program, said: "The very use of molecular methods to produce disease and pest-resistant varieties of some fruits and vegetables is being driven by consumer demand" (Cook 1994). This is because consumers not only demand fruits and vegetables free of pesticide residues, they demand those varieties that allow for pesticide use reductions.

By responding to downstream demand, identity-preserved systems will more closely link producers to consumers and other end users. Thomas N. Urban, President and CEO of Pioneer Hi-Bred International, Inc., who has written and spoken on the implications of identity preservation, noted: "We are getting to the point where we can almost identify certain farmers with certain shelf space" (Urban 1993).

The Role of Intellectual Property in Identity-Preserved Systems

Intellectual property rights will be critically important in identity-preserved systems for livestock, field crop and horticultural varieties. This is because intellectual property rights ensure the preservation and control of the value-added factor through the food chain.

There are two basic ways that intellectual property rights maintain the identity and profitability of value-added proprietary factors of identity-preserved varieties. First of all, intellectual property rights reduce research and development investment risk. This holds true for all commercial products requiring substantial research and development outlays and is the basic policy rationale behind intellectual property laws. The biotechnology industry presents an extreme case in that it is more capital intensive than most and its products easily copied. Thus, plant breeders' rights, trade secrets, trademarks and patents are particularly important in the agricultural biotechnology industry.

Pioneer Hi-Bred Patent Counsel, Michael J. Roth, writes: ". . . we need more protection for the fruits of our research than has traditionally been available . . . By providing a higher level of protection . . . patents help to insulate protected technology against risk, particularly that the technology will be copied by persons who have invested and risked nothing in its creation" (Roth 1994).

Second, intellectual property rights allow those who control the flow of value-added components in the food chain to obtain downstream premiums. A quick look at the percentage of the consumer food dollar spent on upstream versus downstream added-value reveals that the lion's share of profits in the food industry derive from downstream activities. For example, the annual retail market for fresh tomatoes in the U.S. is $3.5 billion versus a $300 million annual retail market for tomato seed.[2]

Identity-preserved products provide downstream added-value, for which the processor and consumer are willing to pay a premium. (Goldberg 1993). Identity-preserved products, separated from their cousins in traditional commodity markets and controlled by proprietary rights holders, will allow a greater portion of the downstream food dollar to flow to upstream actors.

In fact, actors at any point in food chain who obtain proprietary rights in identity-preserved technology can profit from interactions at points upstream or downstream. For example, consider the food processor that contracts out the production of its proprietary identity-preserved variety and then processes and markets an identity-preserved product under its brand name. It also may license out the same identity-preserved technology to upstream research firms.

The distribution of proprietary rights and royalties under these coordinated systems will depend on one's position in the food chain—whether a university, biotechnology firm, producer, processor, packer, retailer, etc. Moreover, the development of a harmonized global intellectual property system as a result of recent changes in the General Agreement on Tariffs and Trade (GATT) will facilitate these interactions on a global scale.

The Calgene Flavr Savr ™ Tomato - An Identity-Preserved System

To illustrate these concepts, let us look at the most famous agricultural biotechnology product on the market today—the Calgene Flavr Savr™ tomato.

In 1984, Calgene, Inc. entered into an agreement with the Campbell Institute for Research to develop technology for production of premium vine-ripened tomatoes. According to the agreement, Calgene would obtain patents on any relevant isolated genes and Campbell Soup Company would receive an exclusive, worldwide license for their use.

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[2]Calgene, Inc. 1995

In February 1989, Calgene, was issued a U.S. patent on the tomato polygalacturonase gene sequence and the use of its antisense orientation. In April 1992, the company was issued a broad process patent covering the use of antisense RNA technology in all plants. In 1991, Zeneca A.V.P., a subsidiary of ICI, Inc., filed and was granted an interference by the U.S. Patent Office between the 1989 Calgene patent and Zeneca's 1986 patent application on a similar technology. All three companies entered into negotiations and in February 1994, a final distribution of rights was determined.

Campbell and Zeneca co-own exclusive rights to grow and use Flavr Savr™ technology for processed tomato products. Calgene Fresh owns exclusive, worldwide, royalty-free rights to produce and sell fresh market tomatoes containing the Flavr Savr™ gene.

Let us see how the Flavr Savr™ production, handling and marketing system places it outside the larger traditional commodity tomato system, commonly known as the "gas green" system.

Flavr Savr ™ or "Vine-Ripe" System

Calgene, Inc. scientists engineered Flavr Savr™ technology into tomato varieties bred in the 1950s for superior taste, but which had fallen out of production because they were inappropriate for the gas-green system. Because the Flavr Savr™ tomato requires special growing, packing and transportation to preserve the vine-ripened taste and consistency factors, Calgene decided to manage the entire system.

Calgene Fresh, a wholly-owned subsidiary of Calgene, Inc., was formed in 1992 to manage the Flavr Savr™ system. The company has entered into year-round production contracts with a number of growers in California and Florida, and expects to have growers soon in Mexico. Under the contracts, Flavr Savr™ growers do not take ownership of the seed or progeny tomatoes.

Contract growers must abide by a set of strict growing protocols that include integrated pest management and nutrient management techniques. The Flavr Savr™ technology allows the tomatoes to be picked ripe. Calgene Fresh sorts the tomatoes into three quality grade categories, the highest quality of which are designated for marketing under the brand name MacGregors®. Calgene contracts with shippers to transport MacGregors® tomatoes at temperatures above 50°F to supermarkets.

Calgene Fresh has developed its own marketing program for MacGregors® tomatoes that uses brand development and support techniques traditionally employed for processed and other branded food items. This involves the use of trained food brokers to sell and support the product in retail supermarkets. Each tomato carries a sticker denoting it as a product of genetic engineering and brochures on the product are available at the point of purchase.

"Gas-Green "System

Most producers of fresh tomatoes in the "gas-green" system grow on contract for a packer/shipper. The varieties used were derived from publicly-released varieties developed for machine harvesting. These tomatoes are picked green and purchased by the packer/shipper, who sorts and packs them using special machinery. Prior to shipping, ethylene gas is applied to induce ripening. The tomatoes are sold to one or two repackers, who in turn sells to the retailer. These tomatoes are shipped at temperatures below 50°E More time is required to take the product to the consumer under the gas-green system because of the middlemen involved.

Comparing the two systems, we can readily see how MacGregors® tomatoes fit Goldberg's description of identity-preserved systems: "The tailor-making of identity-preserved food products allows the input supplier to provide branded ingredients at the farm supply and farm level; these ingredients, in turn, enable both the branded food manufacturer and the private label food retailer ... to differentiate their final products to the consumer" (Goldberg 1993). Here, Flavr Savr™ technology is supplied at the farm level and preserved for the consumer under the MacGregors® brand name. On the other hand, there is no value-added factor preserved from production to consumption in the gas green system and no identifiable relationship between growers and consumers.

IDENTITY-PRESERVED SYSTEMS AND PRODUCTION AGRICULTURE

The mechanism by which the identity-preserved system links producers to the rest of the food chain is the production contract. Contract production in the U.S. is by no means a new phenomenon. Integrated systems based on contract production have existed for some time in poultry, fruit and vegetables and are increasing in hogs where the percentage raised under contract has grown from two percent in 1980 to 18 percent in 1990 (Kelley 1994). It is predicted that an increasing percentage of these contracts will involve identity-preserved varieties. For instance, Thomas Urban expects nearly 25 percent of all corn grain production in the U.S. to be on an identity-preserved, contract basis by the year 2000 (Urban 1991).

Minneapolis attorney Christopher R. Kelley classifies production contracts (here, between producer and processor) into four categories:

Market specification contracts — set the price, quantity and quality of the product;

Production management contracts — give the processor direct control over production methods;

Resource-providing contracts — allow the processor to provide all or part of the inputs, incorporating strict quality standards throughout the production process; and

Vertical integration contracts — completely shift production control to the processor, with the producer supplying only labor, land and other fixed inputs (Kelley 1994).

Production contracts involving protected identity-preserved varieties are licenses. Because such contracts license a specific quantity of the proprietary identity-preserved variety, they are called bailments.[3] For example, the Flavr Savr™ contract producer takes possession of a fixed quantity but no property interest in Flavr Savr™ seeds or progeny. Therefore, as the number of identity-preserved systems involving proprietary varieties and special production practices increases, we would expect to see an increase in the last two types of contracts.

The primary advantage of contract production for both the producer and the contractor is risk management. By controlling the timing, quantity, quality and specifications of production, economic efficiencies may be realized. Coupled with long-term marketing arrangements, these factors can help promote stability. Contract production of identity preserved varieties may provide producers with better returns than those obtainable in traditional commodity markets. Thomas Urban writes, "As opposed to producing a commodity that is then transformed by some portion of the food chain, farmers themselves are going to receive a premium" (Urban 1993) for the identity-preserved factor. For example, I learned that retailers pay twice as much for the Flavr Savr™ tomato as for the gas-green tomato.

There are a number of factors that can impact a contract producer's ability to obtain higher returns. In his book on production contracts, Drake University Law Professor Neil Hamilton discusses an important point about privately negotiated contract production systems — the loss of publicly discovered pricing mechanisms, so that the producer cannot learn the real market value of the products (Hamilton 1995).

Another factor influencing a producer's return under a production contract is 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.

In an effort to improve returns over those available under contract production alone, some producers have moved into value-adding, downstream activities, such as processing and marketing of identity-preserved varieties. For proprietary varieties, this would necessitate a license to grow, process and sell products of the variety.

[3]The legal relationship created in the standard seed production contract is a bailment.

An example of the above is the American White Wheat Producers Association (AWWPA), a marketing cooperative of western and Midwestern wheat producers formed in 1988. AWWPA has exclusive licenses to grow, process and sell flour of two proprietary hard white wheat varieties. Members grow the varieties under contract with AWWPA, which retains marketing rights. AWWPA mills the wheat and sells flour to bakeries and processors. It has a trademark for its flour, which is displayed on wheat products. This eliminates a number of middlemen and has increased members' profits (Burchett 1993).

Another option for producer groups is to obtain proprietary rights in or exclusive licenses to identity-preserved varieties through research agreements or other strategic alliances with the private or public sector. Alternatively, producer groups may contract for research services or establish their own private research institutes.[4]

Traditionally, producers have funded land-grant university research with grants from private commodity groups and with checkoff funds managed by marketing order boards. Until recently, technology developed using these funds was considered a public good and transferred to state industry by state extension services and experiment stations. Today, land-grant universities protect inventions with intellectual property rights, enter into research agreements with and exclusively license technology to the private sector.

The legal status of a commodity group can affect its ability to take a proprietary interest in or license proprietary agricultural technology. For instance, federal and state marketing order boards are part of and serve in an advisory capacity to their respective departments of agriculture. As a result, marketing order boards are not separate legal entities and cannot take a proprietary interest in or license technology for commercial use. On the other hand, commodity commissions are created by specific legislation to perform the same function as marketing order boards but are separate legal entities within state governments and therefore can take a proprietary interest in or license technology for commercial use.[5 &]

Where producer groups choose to continue to fund land-grant university research, should the university give them a preference in licensing proprietary technology generated with such funds?

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[4]For example, a coalition of California dairy industry groups have established a private dairy research institute at the California State University at San Luis Obispo.

Recently, some California state marketing orders have restructured as commissions in part to give themselves the option of owning or licensing the technology they funded independent of the State Department of Food and Agriculture. (See, for example, the Fresh Strawberry Program Act, Cal. F & Agric. Code §§77401-77505).

This is a topic of current debate in California. A 1994 report by the California Commodity Commission[6] criticized the University of California's intellectual property rights and technology transfer policies and questioned the University's commitment to California agriculture:

> The university's preeminent reputation . . . has resulted . . . from its close interaction with commercial farmers and from their strong support and cooperation ... A break in this close connection with and clear commitment to California agriculture increases the likelihood that technology developed with tax dollars or funds provided by private industry, commodity groups and agencies could become equally available to competing industries in other states and nations (California Commodity Committee 1994).

The report gives examples where new technology developed with state commodity program grant money was licensed to an out-of-state competitor before the state commodity group knew about the technology. The report recommends that the university adopt a policy to ensure that research is directed toward developing patents of practical value to California agriculture and that groups sponsoring research have preference in licensing and partnership agreements. The University is currently reviewing its policies with input from California commodity groups.

Conclusion

Identity-preservation is one type of end-use oriented marketing system which is changing the structure of modern production agriculture. Intellectual property rights play a central role in identity-preserved systems because they allow rights holders to reduce investment risk, preserve the identity, and control the use of value-added factors in downstream or upstream arenas. Production contracts are the main mechanism by which producers will participate in identity-preserved systems. Production contracts can reduce risks and offer premium prices, but they also can present new risks such as 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. Such activities will add to the need to re-examine the traditional relationship between the land-grant university and state agriculture. [6]

[6]This committee represents California commodities that are organized under a marketing order, commission, or a related state or federal commodity marketing program.

References

Burchett, L. 1993. A Producer-driven Identity-Preserved Example: Hard White Winter Wheat in Kansas. *Proceedings of the 1993 Soybean Seed Research Conference,* pp. 62-68

California Commodity Committee. 1994. *A Review of the Division of Agriculture and Natural Resources of the University of California*

Cook, R.J. 1994. Biotechnology for the Public Good. In J. Fessenden MacDonald, ed. *Agricultural Biotechnology and the Public Good.* National Agricultural Biotechnology Council, Ithaca, NY. pp. 59-72

Fraley, R.T. 1994. Commercialization of Genetically Modified Plants: Progress Towards the Marketplace. In J. Fessenden MacDonald, ed. *Agricultural Biotechnology and the Public Good.* National Agricultural Biotechnology Council, Ithaca, NY. pp. 33-42

Goldberg, R.A. 1993. The Role of New Technologies in Changing the Global Food System. In G.E. Gaull and R.A. Goldberg, eds. *The Emerging Global Food System: Public and Private Sector Issues.* John Wiley & Sons, New York, pp. 13-22

Hamilton, N.D. 1995. A *Farmer's Legal Guide to Production Contracts.* Farm Journal, Inc.

Kelley, C.R. 1994. Preparing and Using Production Contracts. *Committee Update.* 1994-95(1). Agricultural Law Committee of the American Bar Association General Practice Section

Roth, M.J. 1994. *Old Tools, New Rules: Intellectual Property Law and the Privatization of American Agriculture.* American Association for the Advancement of Science Annual Meeting, February 23, 1994, San Francisco, CA

Urban, T.N. 1991. Agricultural Industrialization: It's Inevitable. *Choices.* 4th quarter, pp. 4-5

Urban, T.N. 1993. The Industrialization of Agriculture. In G.E. Gaull and R.A. Goldberg, eds. *The Emerging Global Food System: Public and Private Sector Issues.* John Wiley & Sons, New York, pp. 25-26

Recommended Reading

Boehlje, M. 1994. *Agriculture in the 21st Century.* Purdue University, Department of Agricultural Economics, Staff Paper #94-29

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Gene Ownership versus Access: Meeting the Needs

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Two developments, which simultaneously and independently occurred in the 1980s, have substantially impacted the way drugs are currently being discovered and developed. First, there was a significant change in the technology employed for drug discovery. Traditionally, drugs were discovered using organs, tissues, cells or extracts thereof in screens to identify active pharmaceuticals. These traditional methodologies have been replaced by the use of technology involving specific molecular targets. These biotechnological targets may be receptors responsible for unique cell interactions associated with a disease or an enzyme that can catalyze a distinct biochemical reaction associated with a disease. The ability to identify and produce these unique proteins by recombinant techniques has resulted, in turn, in a wide range of mechanism-based screens. Of the 40 top selling drugs (worldwide sales 1993), 25 were identified by a specific mechanism of action: 13 were receptor agonists/antagonists; eight were enzymes/protease inhibitors; and four were channel blockers.

Second, the unencumbered availability of the materials and processes used in drug discovery has been noticeably decreasing. Prior to the rapid development of biotechnology, most pharmaceutical or chemical patents claimed active therapeutic agents, intermediates leading to active agents, processes of making active agents and intermediates, and methods of using active agents. The basic methodologies for chemical research were not generally patented. In 1980, Congress passed both the Stevenson-

Wydler Technology Innovation Act[1] and the Bayh-Dole Act[2] . Together, these Acts allowed government contractors, small businesses and nonprofit organizations to retain certain patent rights in government sponsored research and permitted the funded entity to transfer the technology to third parties. The original legislation was expanded in 1983 by Presidential Order[3] to include all government contractors. The 1980 legislation and subsequent amendments[4] (collectively termed Bayh-Dole) permit the contractor to grant exclusive licenses to government-funded contractor inventions. With the passage of the Federal Technology Transfer Act of 1986[5], Congress authorized federal laboratories to enter into cooperative research and development agreements (CRADAs) with private companies. The Act also required federal laboratories to agree in advance to assign or license to the collaborating party patents on inventions made by federal employees in the course of the collaborative research.

The stated intent of Bayh-Dole was to ensure that the patented results of federally funded research would be broadly and rapidly available for all scientific investigation, irrespective of the objectives of the research and the terms under which licenses are granted for the sale of products under the patents. Bayh-Dole effectively shifted federal policy from a position of putting the results of government-sponsored research directly into the public domain for use by all, to a pro-patent position that stressed the need for exclusive rights as an incentive for industry to undertake the costly investment necessary to bring new products to market. As a result, many of the basic materials and laboratory procedures that are universal to biotechnology and modern drug discovery have been the subject of patents and patent applications. As a result, accessibility is restricted.

The biotechnology materials and procedures that enhance drug discovery have been termed Research Tools. Research Tools are defined herein as biological or biochemical materials or processes that are useful for drug discovery and exclude materials or processes when used commercially. Examples of Research Tools include cDNA clones, receptors, monoclonal antibodies, transgenic animals and other inventions that can be used for drug discovery.

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[1]Pub. L. No. 96-480, 94 Stat. 2311 (1980) (codified as amended at 15 U.S.C. §§ 3701-3714).

[2]Pub. L. No. 96-517, § 6(a), 94 Stat. 3015, 3019-27 (1980) (codified as amended at 35 U.S.C. §§ 201-211).

[3]Presidential Memorandum to the Heads of Executive Departments and Agencies, Subject: government Patent Policy, 1983 Pub. Papers 248.

[4]Pub. L. No. 98-620, 98 Stat. 3335 [Trademark Clarification Act of 1984).

[5]Pub. L. No. 99-502, 100 Stat. 1785 (amending the Stevenson-Wydler Technology Innovation Act of 1980).

It is well recognized that one purpose of Bayh-Dole is to permit government funded patentees to grant exclusive licenses for the commercialization of products. This purpose can be accomplished while the broader intent of the Acts — that inventions be utilized as broadly as possible, is met. Accordingly, we believe that a federally funded patentee should grant non-exclusive licenses for Research Tools independent of licenses for products for sale. Further, we believe that the non-exclusive licenses should be available for reasonable fees. This broad access to Research Tools discovered under federally funded research programs by a non-exclusive license acts to foster competition among commercial laboratories to discover and ultimately develop novel human health products, thereby meeting the Congressional intent of Bayh-Dole. Because Merck supports a policy of licensing of patented inventions for research use separately from licensing for commercial development of products for sale, Merck Research Tool inventions are accessible for research purposes.

The current avalanche of genetic information from the Human Genome Project and other sequencing sources promises even greater advances for molecular medicine from Research Tools identified by these programs. With a complete, high resolution map of the human genome and an understanding of the genetic basis for disease, scientists should be able to create mechanism-based drugs that will result in improved therapies for known diseases and new therapies for diseases as yet unconquered. For this to happen in a timely manner, the basic Research Tools required for drug discovery must be readily available to the academic, governmental and industrial biomedical research community. Thus, availability will likely depend on ownership of genes and gene products and the methods of using those gene products.

Ownership of human genes first became a national and international issue when in 1992, the National Institutes of Health (NIH) filed patent applications claiming thousands of partial cDNA sequences which Craig Venter had termed expressed sequence tags (EST) (Adams et al. 1991). The NIH claimed the EST patent applications were filed to preserve a proprietary position for presumed valuable inventions (McGregor 1992). The NIH assumed that patent claims would issue with sufficient breadth to attract licensees that would develop products related to the partial genes. The NIH applications, however, created a worldwide controversy. American scientists associated with the human genome project strongly opposed the filing of EST patent applications because they believed the patents would have a negative impact on genome research (Roberts 1991). The science ministries of numerous European countries were very outspoken about how the patenting of genetic information would likely slow down the human genome project and change the economics of biomedical research. Due to the outcry from the worldwide scientific community and the inability to overcome the U.S. Patent and Trademark Office's (USPTO) rejection of the applications claims, the NIH simply did not respond to actions from the USPTO and the applications went abandoned.

The NIH applications raised questions about the patentability of human gene segments. The USPTO has issued patents claiming isolated and purified DNA (cDNA or genomic DNA) which encode a functional protein of known activity. Indeed, patents have been issued on short DNA fragments that are useful as diagnostics. The issuance of DNA patents requires that a compound (a gene, genomic sequence or cDNA sequence) must have been removed from its natural setting, be new, useful, unobvious and be enabled by the patent application.[6] An invention is considered novel if it has not been placed in the public domain, i.e., is not described in a publication or placed in commerce. The utility requirement can generally be met by demonstrating a particular use, such as a DNA sequence for gene therapy or as an intermediate for the manufacture of the encoded protein with an established function. A nonobvious invention is one that could not have been made with a reasonable expectation of success by a hypothetical person of "ordinary skill" in the relevant scientific field from publicly available information. Enablement requires that a patent application teach one skilled in the scientific area how to make and use the invention. In the case of the NIH partial sequences (EST) as discussed above, the USPTO maintained that the ESTs did not meet the utility requirement nor did the applications enable the inventions.

The Court of Appeals for the Federal Circuit (CAFC) has affirmed the validity of claims to full length cDNA or genomic DNA molecules, e.g., human erythropoietin and insulin like growth factor.[7] Indeed, obtaining a patent on a specific DNA molecule is quite beneficial in developing a patent portfolio around a specific protein therapeutic. In some instances, the protein may be known and not patentable and the only patent protection available will be for the isolated and purified DNA that can be used to make the protein therapeutic. This is important because large proteins may not be economically made by nonbiotechnological means. Product exclusivity through patent protection is required to offset the high research and development costs and the extended time to bring a product to market. The current estimate for this high risk enterprise is an average of 12 years from discovery to market and an investment of over $350 million.

With the lapse of the NIH EST patent applications the subject matter entered the public domain and was available to all researchers. The scientific community hoped that all genomic Research Tools would be readily available for biomedical research. Unfortunately, the privatization of EST research has thwarted this goal.

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[6]35 U.S.C. §§ 100-103 and 35 U.S.C. § 112.

[7]Amgen Inc. v. Chugai Pharmaceutical Co., 927 E 2d 1200,18 USPQ2d 1016 (Fed. Cir.), cert, denied, 502 U.S. 856 (1991) and In re Bell, 991E 2nd 781; 26 USPQ2d 1529 (Fed. Cir. 1993)

Several organizations are attempting to establish proprietary control over much of the sequence data on expressed human genes, including ESTs. Companies such as Human Genome Sciences (HGS) and Incyte are generating large EST data bases and are licensing access on an exclusive or non-exclusive basis to commercial entities (Dickson 1994a; Gen. Tech. News 1994). HGS initially maintained control over the utilization of the cDNA resources in their database and restricted access to collaborators, such as SmithKline Beecham, who were willing to invest significant sums of money for sequence information and rights to patented genes. Recently HGS has allowed academics limited access to the database but only if the institution agrees to allow HGS to develop any product identified by the use of the information gained from the database (Dickson 1994b). Unfortunately, this type of private ownership may prevent genomic scientists from pursuing full-length sequencing, mapping, and gene-based discoveries that would realize the goals to the Human Genome Project.

Merck has taken the view that the information represented by ESTs should be made broadly available with no commercial obligations. Indeed, access to the ESTs plus the corresponding physical cDNA clone will provide the key Research Tools that will speed the development of new biomedical knowledge. This knowledge should lead to new therapeutics for a wide range of diseases as the underlying pathophysiological mechanisms are better understood. The medical and commercial results of these efforts will benefit all interested parties, while providing opportunities and preserving incentives for investment in gene-based product development.

To this end, Merck has organized a collaborative effort termed the Merck Gene Index Project. This effort will make cDNA resources rapidly available to all scientists, for gene identification and mapping (Williamson and Elliston 1994). The Merck Gene Index will be a catalog of sequence data and identified clones arrayed from numerous cDNA libraries representing various organs and tissues and a variety of developmental stages. All scientists, whether public or private, will have full access to this standard set representing one clone per unique expressed gene. These clones will be characterized by single pass DNA sequencing and will be arrayed into microtitre plates and on filters as a publicly available resource. In cooperation with the IMAGE consortium (Integrated Molecular Analysis of Gene Expression), coordinated by Greg Lennon of Lawrence Livermore National Laboratory, a set of appropriate clones will be identified for sequencing by Robert Waterston, Richard Wilson, and their colleagues at the Genome Sequencing Center of the Washington University School of Medicine in St. Louis, Missouri. By identifying the repetitive and uniquely expressed genes, the number of clones that must be sequenced to capture all unique genes in a given sample should be reduced by an order of magnitude.

Washington University will generate sequence data from both the 5' and 3' ends of about 200,000 individual cDNA clones. The 3' end sequences will help facilitate mapping and full-length sequencing of specific cDNAs on human chromosomes, and facilitate the identification of a minimal set of unique gene cDNAs. The 5' end sequences will assist in identifying human cDNA sequence similarity to proteins of known function in existing databases. The new sequence data generated by Washington University will be submitted regularly via Database EST to Genbank (managed by the National Center for Biotechnology Information) where all interested researchers will have immediate and unrestricted access to the data, not only in the U.S., but also through Genbank's collaborative arrangements with its international partners, including the European Bioinformatics Institute, National Center for Genomic Resources and DNA Database of Japan. All users will be asked, though not required, to contribute results obtained using the Merck Gene Index data and/or clones to appropriate public databases.

The set of roughly 200,000 cDNA clones to be sequenced by Washington University will also be available from appropriate commercial and not-for-profit organizations, in the form of polymerase chain reaction (PCR) products gridded onto nylon membranes, and as individual clones and sets of clones in 384-well plates. These resources will then be distributed at reasonable cost via established networks to researchers who wish to do sequencing and mapping of individual genes or sets of genes, or for any research purpose.

This effort is anticipated to characterize between 50 percent and 85 percent of the unique expressed human genes, and to increase dramatically the amount and quality of publicly available sequence information on expressed genes. Scientists worldwide will have ready access to and be able to exploit particular clones as singletons or sets. The associated bioinformatics effort will ensure that the data generated are also captured in standardized fashion and made broadly available in public databases. These subsequent efforts using the Merck Gene Index as a research resource will likely lead to the identification of nearly 100 percent of expressed human genes.

The continued expansion of biomedical science and the discovery and development of unique highly specific therapeutics will depend on the availability of Research Tools to the academic, governmental and commercial research scientists. This can best be accomplished by having federally funded Research Tools available non-exclusively and by encouraging collaborations between commercial laboratories and academic and governmental laboratories to develop Research Tools, such as the Merck Gene Index. This broad access to Research Tools will advance science, accelerate the progress of medicine, and foster competition among commercial laboratories to discover and ultimately develop new human health products that will benefit all.

References

Adams, M.D., J.M. Kelley, J.D. Gocayne, M. Dubnick, M.H. Polymeropoulos, H. Xiao, C.R. Merril, A. Wu, B. Olde, R.F. Moreno, A.R. Kerlavage, W.R. McCombie, and J.C. Venter. 1991. Complementary DNA Sequencing: Expressed Sequence Tags and Human Genome Project. *Science.* 252:1651-1656

Dickson, D. 1994a. 'Gene Map' plan highlights dispute over public vs. private interests. *Nature.* 371:365-366

Dickson, D. 1994b. HGS seeks exclusive option on all patents using its cDNA sequences. *Nature.* 371:463

Genetic Technology News, 1994. 14(11):2

McGregor, M.L. 1992. The NIH Patent Dispute in Brief. *Biotechnology Law Report,* p. 127

Rhein, R. 1994. *Biotechnology Newswatch*

Roberts, L. 1991. Genome Patent Fight Erupts. *Science.* 254:184-186

Williamson, A., and K. Elliston, 1994. Ownership and Human Genome. *Nature.* 372:10

Farmer's Rights: What is Fair?

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One evening as I walked to the pasture to herd my cows home for milking, I took a detour through my managed forest. What a thrill to come upon two young great horned owls perched on a fallen log. They solemnly allowed me to come within thirty feet of them before flying to a higher perch where they could still stare at me while 1 stared at them.

Raptors such as these giant owls, as well as hawks and eagles, have been making a comeback in this area of Wisconsin after all but disappearing a dozen or more years ago. DDT and like compounds had concentrated in their bodies and destroyed their reproductive capabilities. Banning the use of DDT finally allowed them to make a slow comeback. However, this past winter 14 bald eagles died in my county, all in an area where we have regularly observed them feeding on dead animals from confinement hog facilities. Laboratories reported no traces of poison, yet a mysterious poisoning remained the number one suspect in the cause of the deaths.

Are our raptors again in danger of extinction? Are we going too far in the use of questionably tested products to treat disease-prone livestock in confinement facilities? Are genetically engineered pork growth hormones adequately long-term tested?

In a lifetime of farming, I have learned some expensive lessons. Some methods and technologies are helpful, while others create more problems than benefits. Working with "Mother Nature" has been a much more productive and stress-free route than continually fighting her and upsetting her system of checks and balances. My farm is now more productive, more sustainable, and increasingly more environmentally and ecologically correct than any farm in this region. We put every acre of our farm to its highest and best sustainable

use, whether it be trees, pasture or cropland. In any technology I incorporate into my farm operation, I try to direct all decisions in a manner that has a positive impact on all farmers, be they in Asia, Africa or any continent.

People of the land — farmers and indigenous cultures — have a treasure of knowledge based on common sense experiences. How does anyone put a price on the contributions of generations of farmers in selecting plants for higher productivity and better quality? Using hypothetical scenarios to justify taking ownership of genes, information and other living material are both unethical and immoral. We farmers and indigenous peoples have certain rights to health, happiness, land and self-determination. Attempts by others to jeopardize our way of life, our culture, or in any way significantly alter our ability to make a living on our land is an assault on our basic rights.

Some persons have had almost unlimited access to formal education combined with other opportunities. These advantages do not ensure that they are any more intelligent or superior in decision-making than people of the land. They need to be sensitive to farmers, and make a sincere effort to be "in touch." At a recent urban/rural conference in our rural area, for example, some of the farmers (several highly educated) felt ignored and put down by some of the college people who assumed they were ignorant. Although I assured them it was not intentional, for many non-rural people it is a common perception.

People of the land, including indigenous cultures, have a treasure of knowledge based on their common sense, their survival skills and their cultural heritage. They should have the dominating decision-making power to alter their way of life, their culture or their ability to stay on their land. Patenting knowledge and information can also be judged by some as stealing from the past.

Their common sense life experiences, combined with their cultural heritage, qualify the people of the land to maintain ownership of all of their resources. Sometimes resources are held in common, based on community, cultural or tribal history. In these instances, all people need a long period of discussion about how any changes in the economic and social structure may affect them before they make decisions.

Intellectual property rights is somewhat of a misnomer. It is not a *right.* Rather it is an *agreement*, a *sharing,* or a *leasing*. Any taking or patenting of genetic information or material should be dis-allowed and replaced with a fair rental contract, if a consensus can be reached.

We must slow this ruthless rush to force new products and technologies onto the market. Unlike some other progressive countries, the U.S. refuses to consider the social and economic consequences these products and technologies impose on our society. We need to work our consciences. Ignoring the societal consequences dehumanizes our society and destroys the dignity of all who are left out of the process, and they suffer greatly as a result.

Dignity is already being taken away from farmers and other basic producers of food and fiber. When the cost of growing and or producing food is higher than what the farmer receives, there is no dignity or value in that food or its production. It has a minus value. Approximately 75 percent of the farmers in this country are now in this crisis situation. They are holding on by a slave-like schedule that forces them to work off the farm to make up for the losses on their farms. We farmers are fast becoming part of the poverty and oppression that strangles our so-called Third World neighbors in Central America, South America, Africa and Asia.

When dignity is taken, pride and hope also disappear. People without dignity cannot help themselves — they can only struggle to survive. Desertification, destruction of the environment, and eventually the survival of the earth itself is put into grave danger. There are plenty of resources to provide a dignified living for all of us. The rich could still be rich — they simply do not need to be "filthy" rich!

Our policies, our research and our technology need to be directed toward a quality of life that enhances the dignity of all people on this planet, toward our children and our children's children. We need to be repairing the damage to our earth and our society before we rush headlong at "creating" new "weeds" that pose grave questions for the future.

The Webster's New World Dictionary definition of a weed is "a plant out of place." It could also be used to describe a product or technology out of place. As a qualified well-pump installer, I am very aware that more than 58 percent of all water wells in the U.S. are now polluted with commercial and farm chemicals. It may require 30 to 100 years to clean and make them safe, if ever. This pollution came from chemicals that were largely applied 10 and 15 years ago, while the pollution from increased usage since that time is yet to be seen.

Another weed example: The fast growing California Pinion Pine was introduced years ago as a better tree crop in the steep mountains in the Basque country of Spain. Spending some time with friends in that region three years ago, the tree farmers repeatedly showed me the Pinion Pine stands as not only a failure, but as depleting the nutrients of the shallow mountain soil. After the Pinion Pines were harvested, the soil was so depleted that no trees would make any worthwhile growth on these areas. They learned the expensive lesson that only native varieties could continue to grow and produce profitably and sustainability.

Farmers and indigenous people have been misled by sales people who assured them that certain farm chemicals were so safe that they sometimes drank a glass of atrazine, for example, to prove it. Atrazine is now proven to be carcinogenic, polluting much of our drinking water in the Midwest. We need to keep in mind that unethical researchers, companies and individuals hurt the image of all good researchers and scientists.

The ethical and moral implications of emerging technologies need to be thoroughly examined and weighed as to their impact on cultures and economies. Will the economic and lifestyle impact be pleasantly progressive and stable, or will the impact be devastating to certain regions, countries or cultures? As an average American citizen, I need to know how my 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? We must not allow governments to use food as a weapon to control and subjugate other countries or regions.

If we all do not take responsibility for the long-term problems following shortsighted decisions on patenting life forms and intellectual property rights, we will eventually all be losers. The earth is in grave danger; the land and the oceans are becoming polluted. Farmers in this country and around the world are being pushed off their land in record numbers. When large numbers of people are losing their rights and their land, we find a recipe for terrorism from which none of us can escape. People without hope feel they have nothing to lose by fighting back with violence. Forcing people off the land only creates more urban and rural ghettos, which will eventually drag us all down.

This rural crisis fuels rapid growing support for the militia and patriot groups that feel this country has betrayed them.

A serious problem is the growing sentiment to cut funding for public research. Legislators and congress people are responding to this sentiment and are proposing deep cuts in public funding for research in institutions of higher learning. Our country needs more public funding for research, not less. We need to balance the profit-driven motives of industry research with public research for the common good.

Historical lessons from Europe should remind us that any country that loses its family farm system of agriculture soon suffers a collapse of its entire economy. It then takes several hundred years to restore the family farm system and along with it — the economy.

Ownership of Biodiversity: A Developing Country's Perspective on an Open International Debate

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The life sciences are changing at a rapid rate in their fundamental character. These changes are of two principal kinds. First, tremendous technical advances have been realized over the past couple of decades. It is now possible and, indeed, is common practice to transfer genetic material between completely dissimilar organisms. It is also possible to isolate and multiply for commercial use parts of organisms to, for example, mass-produced chemicals that are otherwise produced in much smaller quantities by plants. The second change, intimately connected with these scientific breakthroughs, is a strong and escalating trend toward the commercialization of the life sciences (Belcher and Hawtin 1991).

As a consequence, since the mid-1980s, the main industrialized countries have started international negotiations to encourage (or to force) the rest of the world to reduce unauthorized diffusion of new technologies. The risk of having their intellectual property pirated elsewhere would deter companies from exporting their products and technologies. It was concluded that the absence of strong intellectual property protection performs as an effective trade barrier (Jaffe and van Wijk 1995).

In this context, the protection of biological innovations was introduced in the GATT (General Agreement on Tariffs and Trade) talks around 1990, and has become the subject of specific provisions in the final agreement. In this way, an actual requirement for membership in the World Trade Organization, according to the Uruguay Round of GATT, is full adoption of the agreement on Trade Related Aspects of Intellectual Property Rights (TRIPs). TRIPs sets

international standards for protection. Patents shall be available for any inventions in all fields of technology. Excluded from patent protection may be plants and animals other than microorganisms, and essentially biological processes for the production of plants and animals, other than nonbiological and microbiological processes. However, protection for plant varieties shall be provided either by patents or by an effective sui *generis* system or by any combination thereof (GATT 1994).

TRIPs has brought some peace of mind to those promoting stronger protection of intellectual property rights for biological innovations. But a concern remains: The access to genetic resources and the possibility of adopting a certain degree of control over these resources through different types of ownership. Although considerable progress has been made in developing an international framework for the conservation, use and access to plant genetic resources, it is still unclear if plant genetic resources are subject to ownership. It is also unclear to what extent developing countries, where an important part of biodiversity concentrates, can make actual profits from sovereign rights contemplated in the Convention on Biological Diversity. This paper presents a perspective from the South to these questions.

From a Free Flow System to Sovereignty

During the 1970s, the United Nations Food and Agriculture Organization (FAO) Commission on Plant Genetic Resources was established as an intergovernmental policy forum. Although the FAO's involvement in genetic resources dates back several decades, it was in 1983 that member governments established the International Undertaking on Plant Genetic Resources. The Undertaking is a nonbinding agreement to cooperate in the conservation of genetic material and to work together for its sustainable development. Regarding the ownership and control over plant genetic resources, the Undertaking declared all germplasm, including breeders' lines and elite varieties, as common heritage. Most developing countries, and many developed countries, adhered to the Undertaking, but it had no legal standing. The U.S. did not adhere to the Undertaking, even after the modifications made later (Menon 1995).

Major changes concerning access to genetic resources have been taking place within the Commission. As mentioned before, according to the 1983 FAO International Undertaking on Plant Genetic Resources, common heritage meant free access. Article 5 of the Undertaking stated that adhering governments and institutions will make genetic resources under their control available "free of charge, on the basis of mutual exchange or on mutually agreed terms." In 1989, the Undertaking was modified through the FAO resolution 4.89 on an agreed interpretation of the Undertaking including a recognition of breeders' rights and farmers' rights, and resolution 5.89 on farmers' rights. Resolution 4.89 clearly stated that the term "free access" did not mean "free of charge." The

last FAO conference, held November 1991, discussed another amendment to the Undertaking that endorsed "that nations have sovereign rights over their plant genetic resources and that breeders' lines and farmers' breeding material should only be available at the discretion of their developers during the period of development."

"In other words, in less than a decade, the position had taken a 180 degree turn" (Menon 1995). This constitutes the first international agreement to recognize States' sovereign rights with respect to plant genetic resources, as clarified by resolution 3.91. Under these last provisions, countries adhering to the Undertaking agreed to confer access to the samples of genetic materials under their control only for specific purposes, e.g., scientific research, plant breeding or conservation. This clearly excludes access with an aim to reproducing the materials for commercial purposes, such as for propagating seeds (Correa 1994).

Plant Breeders' Rights, as provided for under UPOV (International Union for the Protection of New Plant Varieties) are not incompatible with the Undertaking. No reference is made regarding the compatibility of the Undertaking with the patenting of plant genetic resources. The granting of patent rights implies the restriction on the access to protected materials greater than in the case of breeders' rights. The compatibility of the Undertaking with patent rights is likely to be discussed in the framework of the ongoing process of the FAO Commission on Plant Genetic Resources. "Divergence's of opinion may be anticipated, since many developing countries seem to view patenting of plants and plant varieties as incompatible with a policy of development and sustainable use of plant genetic resources" (Correa, 1994).

The Convention on Biological Diversity: From Recognition to Compensation

The Convention on Biological Diversity was adopted at the Earth Summit in Rio de Janeiro, in June 1992, which was organized to address a broad range of environmental problems. The Convention represents an attempt to balance the interests of the gene-rich South with those of the gene-poor but technology-rich North. In December 1993, the Convention became, unlike the FAO's International Undertaking, a legally binding framework for conserving and utilizing global diversity. It recognizes "national sovereignty" over all genetic resources, as well as the need to compensate developing nations for the resources that they have historically donated to the development of the world's agriculture.

The Convention represents an agreement that grants access to those resources in exchange for compensation and access to technology. Article 1 of the Convention describes its objectives. They include conservation of biological diversity, sustainable use of its components, fair and equitable sharing of the benefits arising out of the utilization of genetic resources, through (Siebeck 1994):

Appropriate access to genetic resources;

Appropriate transfer of technologies (taking into account all rights over those resources and to technologies); and

Appropriate funding.

Article 3 of the Convention affirms that States have the sovereign right to exploit their own resources pursuant to their own environmental policies. Article 15 addresses access issues and states that the authority to determine access to genetic resources rests within the national governments and is subject to national legislation. This is elaborated as follows (Mugabe and Ouko 1994):

States shall facilitate access for environmentally sound use;

The access shall be subject to prior informed consent and based on mutually agreed terms; and

The Convention provides for the sharing of benefits derived from genetic resources with the country of origin, or the country providing such resources, if required in accordance with the convention.

The right of access by other contracting parties is, thus, dependent upon the conditions established by the legislation and competent authorities of each country. It is also subject to the country's prior consent, provided further that "mutually agreed terms" are reached between the parties. This effectively implies that future transfers of genetic resources will be made under material transfer agreements designed to protect source nations' interests in any resulting profits. Under the compromises of the Convention, this international sovereign right applies only to genetic resources possessed in *in sui* collections. Resources already outside the nationals as in international repositories, are not subject to such rights (Barton 1994).

Another obligation assumed by contracting parties is to provide . .in the case of technology subject to patents and other intellectual property rights . . ." for an "adequate and effective protection" of said rights (Article 16). This article may be read as requiring the patentability of genetic resources, but only defines the conditions of protection if and when such a protection is conferred (Correa 1994).

An obligation is also stated for recipients of genetic resources to allow and facilitate access to technologies on mutually agreed terms and limited to technologies derived from the use of genetic resources. Intellectual property protection, as contemplated in Article 16, limits release of technology. There are no provisions for compulsory licensing (Siebeck, 1994). In this way, "the Convention, in a provision that is carefully balanced but lacks clear logic, also defined a developed-world duty to transfer technologies that are relevant to the conservation and sustainable use of biological diversity or make use of genetic resources. This is to be done in a way consistent with the adequate and effective protection of intellectual property rights" (Barton 1994).

This contradiction regarding the access of developing countries to technologies of developed countries may have profound implications for the former. According to Walter Jaffe (1994), biodiversity offers interesting possibilities for introducing new biotechnologies and investments from the North, but to capitalize these possibilities developing countries require substantial and sophisticated scientific and technological resources. Unless developing countries rapidly create such capacities, the exchange with the North will take place in a very inequitable way, preventing access by developing countries to the technologies they require for sustainable use and conservation of their resources.

The financial needs of the Convention will be subscribed to primarily by the developed countries. These are to meet developing country expenses on conservation, as well as their access to technology. They could be drawn upon to pay for royalties. It seems quite wishful to assume that Global Environment Facility funds, created for this purpose, will be enough to enable developing countries to access the technologies they need to achieve the general objectives of the Convention.

It is therefore hard to imagine how national sovereignty over genetic resources can be implemented in countries that lack the legal infrastructure and, even more critical, that are not even aware of the diversity, quantity, location and potential of these resources. Accepting that it has been a major step for developing countries to get international recognition of the sovereignty and compensation for the value of biological resources, it is essential to keep working 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.

For the latter objective, it seems essential for developing countries to monitor experiences like the famous Merck-INBIO agreement. Under this deal, INBIO agreed to inventory and supply samples of plants, microorganisms and animals collected from the Costa Rican rain forests over a period of two years. The contract gave Merck & Co., Inc., the exclusive rights to screen, develop and patent new products from these resources. In return, Merck agreed to pay INBIO one million dollars and share five percent of the royalties arising from the sale of products derived from these biological materials. This agreement drew criticism from many different writers and policy analysts. The main criticism has been directed at the fact that INBIO is a private organization and therefore had no rights to lay claims to what is seen as national heritage (Menon 1995). Nevertheless, the agreement constitutes a first attempt to solve the problem of implementing effective economic compensation for access to the genetic resources of the South.

Another interesting example comes from another drug company, Shaman Pharmaceuticals. The company announced its intention to return a percentage of profits back to all countries and communities it has worked with after

any product is commercialized. Compensation will be funneled through the Healing Forest Conservancy, a nonprofit organization founded by Shaman for the conservation of biodiversity and the protection of indigenous knowledge. Shaman's research has already led to some patents. The company recognizes that the resulting royalties are based upon its own contribution and that of the communities from whom it received medicinal plants. The company has developed contracts with some indigenous communities in Latin America. However, it could be some time before it will be possible to determine the benefit of the arrangement for the communities involved (Crucible Group 1994).

These two cases do not constitute models for developing countries to follow, but they have the merit of pioneering an non-exploited field. In my opinion, the worst position to adopt before the possibility of negotiating material transfer agreements of this nature is the paralysis from analysis. Some institutions from developing countries are losing real opportunities because of their passive attitudes and the fear of losing the "treasure of biodiversity." This attitude shows that these institutions are forgetting a basic mathematical truth: a small percentage of something is always greater than 100 percent of nothing.

Recognition of Farmers' Contributions to Biodiversity and Agricultural Technology

Since the early 1980s, a part of the South-North controversy over genetic resources has centered on questions of equity in the distribution of benefits arising from the use of plant genetic resources. On one hand, developing countries have questioned the fairness of assigning intellectual property rights to those who breed new plant varieties, while the work of farmers who have generated the plant diversity that constitutes the basis for modern breeding is not legally recognized. On the other hand, industrialized countries have stressed that plant breeders' rights and patents are not a form of compensation but rather an incentive for innovation (Jaffe and van Wijk 1995).

The contribution made by generations of farmers to the conservation of germplasm and the improvement of species has been recognized by the international community, particularly under the FAO International Undertaking on Plant Genetic Resources and the Convention on Biological Diversity. Indeed, the dispute was partly resolved when, within FAO, the rights of farmers in developing countries were acknowledged in order to counterbalance the plant breeders' rights granted in industrialized countries. Farmers' rights were defined as rights arising from contributions of farmers in generating plant genetic resources, particularly in the centers of diversity, and have the purpose of ensuring full benefits to these farmers and supporting the continuation of their contributions (FAO 1989). An International Gene Fund would be created to give a concrete and substantial basis to the farmers' rights.

But even when the farmers' contribution to agricultural innovation is widely recognized[1], the way of compensating this contribution remains in the dark. The International Gene Fund failed to materialize, although it had the merit of bringing the issue to the international political agenda. The concept was further discussed during the Keystone International Dialogue on Plant Genetic Resources (Keystone International Dialogue on Plant Genetic Resources 1991), and during the Earth Summit on Environment and Development in 1992. The Convention, however, follows the principle of national patrimony and recognizes sovereign rights of States (Jade and van Wijk 1995). According to Menon (1995), it is essential to recognize not only the sovereignty but also the result of the work of many generations of peasants as a common contribution to innovation. For this reason, the implementation of FAO's farmers' rights concept should be given greater attention as a source of ideas to materialize the compensation to farmers.

Such rights were not conceived by the FAO Conference as an exclusive right, but as a right to obtain compensation (Correa, 1994). This fits the situation in which the rights are attributed not to individuals but to a collective entity, and to cases in which the administration of the remuneration is administered by a collective organization.

An example of implementation of farmers' rights at the national level is contained in a draft law on plant varieties protection under review in India. According to this document, a National Community Gene Fund would be established. Its funding would be partly supplied by a royalty paid by the seed industry, based on the sales of protected varieties. The funds would be used in trust of Indian farmers for collecting, evaluating, upgrading, conserving and utilizing genetic diversity.

This approach at the national level is certainly an important step, constituting a collective compensating system with impacts in the long run on farmers' communities. However, the collective mechanisms do not solve the problem of compensating farmers at the global level, given the global nature of the values of germplasm farmers provide (Correa 1994).

Internationally, it is essential that intergovernmental negotiations address the creation of a mandatory funding mechanism to recognize, reward and protect the contributions of local communities, farmers and indigenous people (Shand 1993). It has to be understood, however, that such a task will demand a change in the attitudes of negotiators, a greater amount of good will, and a lot of creativity.

'In a recent survey conducted by the author, managers of Mexican seed companies were interviewed and their answer to an explicit question about the contribution of land races to their breeding programs states clearly the essential role of these resources. Company managers also agree that it is important to recognize farmers' contributions and even compensate them economically, but there is no agreement or new ideas on the way to do that.

References

Barton, J.H. 1994. Introduction to International Issues. *Intellectual Property Rights,* Agricultural Biotechnology for Sustainable Productivity for International Development Workshop Series. USAID. Washington

Belcher, B. and G. Hawtin. 1991. A *People, Plants and Patents. The Impact of Intellectual Property on Trade, Plant Biodiversity and Rural Society.* International Development Research Centre. Ottawa

Correa, C.M. (1994), *Sovereign and Property Rights over Plant Genetic Resources.* FAO Commission on Plant Genetic Resources, Background Paper 2. Rome.

Crucible Group, 1994. *People, Plants and Patents.* International Development Research Centre. Ottawa

Food and Agriculture Organization (FAO) of the United Nations 1989. *International Undertaking on Plant Genetic Resources.* CPGR/89/Inf. 2, Rome. April

General Agreement on Tariffs and Trade (GATT) 1994. *Final Act Embodying the* Results *of the Uruguay Round of Multilateral Trade Negotiations',* Marrakesh, Geneva. April 15

Jaffe, W. 1994. The value of biodiversity. *Symposium on Biodiversity, Biotechnology and Sustainable Development.* San Jose, Costa Rica. April 12-14

Jaffe, W. and van Wijk, J. 1995. The impact of Plant Breeders to and Transfer of Genetic Resources; *Int.J. Technology Management.* 10 (2-3):311-324

Keystone International Dialogue Series on Plant Genetic Resources. 1991. *Final consensus Report: Global Initiative for the Security and Sustainable Use of Plant Genetic Resources.* Oslo Plenary Session. Keystone, CO

Menon, U. 1995. Access to and Transfer of Genetic Resources; *Int.J. Technology Management.* 10:2-3

Mugabe, J. and Ouko, E. 1994. Control over Genetic Resources; *Biotechnology and Development Monitor.* 21:6-7

Shand, H. 1993. *1993: A Landmark Year for Biodiversity or Bio-Piracy?* 17:24

Siebeck, W. 1994. The Convention on Biological Diversity: In *Intellectual Property Rights.* ABSP Workshop Series. USAID. Washington

Access: Bartering and Brokering Genetic Resources

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The intergovernmental committee that negotiated the Convention on Biological Diversity (CBD) (United Nations Environment Program 1992) at the United Nations Environment Program (UNEP) generally lacked agricultural representation from most countries. Thus, the representatives and negotiators embarked upon their negotiations with considerable misinformation and a lack of understanding which created an atmosphere of conflict: South vs. North. An example is the Merck-INBIO Agreement in which Merck & Co., Inc., paid to INBIO in Costa Rica a flat sum of $ 1 million to help seek biodiversity which could be analyzed for bioactive compounds and, if successfully marketed, would bring royalties. There was a general lack of understanding that biodiversity prospecting for other uses might require or take different approaches, particularly that for agricultural biodiversity where the genes of interest must also be very specific and must fit other criteria of the breeders. Breeding agricultural plants is a dynamic process, not extractive. The germplasm must provide specific trait(s), be able to be crossbred and be free from tightly linked undesirable traits.

At the same time as the negotiation of the Convention was underway, the Food and Agriculture Organization (FAO) of the United Nations continued its effort to resolve the decade-old debate in its Commission on Plant Genetic Resources (CPGR): Who owns the world's agricultural genetic resources? The CPGR was established in 1983 to implement the FAO's International Undertaking (IU) on Plant Genetic Resources, an FAO Resolution (8/83) (FAO 1983) to conserve and sustainably utilize agricultural genetic resources. The IU was triggered, to a large extent, by the expansion of breeders' rights protection as more countries joined the treaty of the Union for the Protection of Newly Developed Varieties (UPOV). Social activist groups working with peasant farmers, such as the Rural Advancement Foundation International, challenged the equity when companies in developed countries obtained property protec-

tion on cultivars of major food crops after inserting germplasm (particularly genes for disease and insect resistance) from farmer varieties (landraces). The companies made no provision for compensation to those farmer communities or countries from which the genes were obtained. (There has been no formal linkage in the international community between the exchanges and the utilization.) Some now call this proposed compensation, farmers' rights.

The FAO's IU attempted to make all germplasm, including that of private companies, freely available to all parties worldwide. Countries having strong private sector interests opposed this and did not sign onto the IU or did so with specific reservations to protect the private sector. Throughout a ten year period, generally nonconstructive debate ensued. The Keystone International Dialogue on Plant Genetic Resources, initiated in 1988, brought consensus in some areas relative to support for conservation in recognition of farmers' rights, recognition of breeders' rights, and the need for benefit-sharing with providers of germplasm (Keystone International Dialogue Series on Plant Genetic Resources 1991). These consensus points became translated into agreed interpretations to the FAOs IU which were added to the original IU as attachments. Farmers' rights are defined in the second addendum (1991) to the FAO IU, which does not advocate direct payment to farmers. The 1989 attachment clearly acknowledges the need for a fund to preserve genetic resources, such as the FAO fund — a non-existent, voluntary but authorized fund — to support conservation and utilization to recognize farmer contributions over the many years.

The FAO Conference passed the voluntary but rather regulatory International Code of Conduct for Plant Germplasm Collecting and Transfer (FAO 1993). Besides stating some ethical principles for collectors and genebank managers, this Code suggests mechanisms for receiving benefits to the donors.

One item pressed to closure in October 1994 was the agreement by the International Agricultural Research Centers (IARC) to place their collections under the auspices of the FAO Commission. The issue of interest to all is the access to the large collections of the major food crops held at the IARCs. Developing country germplasm in the collections will still be available, but restrictions prevent any property protection placed on them directly by recipients. It does not deal with derivatives, and not everyone is satisfied with the agreement.

Current

The Commission on Plant Genetic Resources is negotiating a revised IU since some of its text is not in harmony with the Convention on Biological Diversity. A one-week extraordinary session of the normally biennial CPGR was held in November 1994, and country representatives expressed their expectations and positions on the integrated text of the IU and its annexes. Some countries were represented by some of the same negotiators as for the CBD, and the understanding of agricultural issues was little advanced. Additionally, many

developing countries were represented only by the local permanent FAO representatives who have varying degrees of understanding of the issues at stake or of the related activities in their countries. The discussions went nowhere. The CPGR held a two-week session in late June 1995, and resumed negotiations on the 1U. The focus of the negotiating session was on the most difficult issues, thereby writing a prescription for potential failure. Property rights issues will remain very contentious as the issues will focus on access to genetic resources and farmers' rights. All of this will be conducted in a political context — not scientific, not pragmatic, and not logical such as a concern for food security.

The success of these negotiations will likely impact heavily on future advances in crop breeding and production agriculture. Restricted access will affect developing and developed nations alike, depending on the crop. Since no nation's agriculture is without interdependency of others, there will be many factors involved in what appears like a Chinese checkers match. For example, 60 percent of the world's food production is from crops and their relatives originally from Central and South America (maize, potato, sweet potato, cassava). But, rice from Asia is the world's most important cereal, followed by wheat from Western Asia. It is hard to say how the African continent would fare since only 34 percent of its production is from crops native to Africa, primarily sorghum and millets. South America, at 94 percent dependency, is heavily dependent on the corn and beans from Central America and barley, oat, rice, wheat and soybean from different parts of Asia. Of course, the U.S. with its native sunflower — developed as a crop by the Russians — plants more than 99 percent of its crop acreage to non-native crops.

Access to genetic resources has been provided by formal exchanges between countries and less formal exchanges by institutes and scientists. Scientist exchanges have generally been with other scientists after visitation or meeting in scientific conferences. These exchanges are probably closest to the "mutually agreed terms" of the CBD since each has an expectation and there is reciprocity. The CBD is more oriented to bilateral arrangements which is the more normal way most exchanges are made. However, the rules of the game, until now, have been essentially multilateral, that is, there is a commonly accepted basis for exchange. If the CBD were to hold a strict accounting of exchanges, the lack of a multilateral arrangement would play hard on the countries that could least afford access to some needed genetic resources.

There is need for information and rational action on all fronts. The Conference of Parties to the Convention needs to understand the delicate balance between breeder access to genetic resources to thwart new pest breakouts and stable food supplies at a reasonable price. There are many questioning the global commodity exchange situation after the Uruguay Round of General Agreement on Tariffs and Trade (GATT) and its new successor World Trade Organization. Should all nations develop their own

food production capacity? Some feel that with the increasing pressure on the environment, those countries best able to produce food under intensive agriculture should increase that sustainable capacity. Thus, import-dependent countries would remain so. However, no country feels comfortable being unable to control its food supply train. The U.S. exports approximately 60 percent of its wheat, 20 percent of its corn, and 35 percent of its soybean.

The U.S. Department of Agriculture (USDA) policy for the free flow of germplasm continues for the National Plant Germplasm System. During the period of 1990 through 1994, 182,678 samples were distributed to foreign requesters, about 92 percent to foreign public institutions, including the gene banks for repatriation. More than 41 percent of the germplasm was advanced germplasm and elite cultivars which went to public institutions for inclusion in their breeding programs. This is a significant contribution to development programs in other countries.

However, if de-registration of current pesticides were to occur without substitutes, U.S. crop losses would greatly reduce production and that left for export might not meet quality requirements of the importers. The impact would be considerable in international markets and the prices we all pay for grain and food. The impact on the U.S. for lack of access to genetic resources to provide genetic resistance to insects and diseases could thus be substantial. The ownership and exchange issue must be solved forthrightly.

The U.S. is greatly divided in its acceptance of the property rights on genetic resources. Institutions and breeders are divided, not necessarily along institutional lines. States are pressed financially to support crop development on crops not sufficiently lucrative to the private sector. Even fees from sales of those principal cultivars must support more than just those crops. However, most organizations feel that they could provide royalties when there has been an identifiable and substantial contribution from a plant to their new cultivar. If there is a benefit to the farmers, the farmers would justifiably pay for it in increased seed prices. However, depending on the market, they may not benefit when they sell the crop. With the increased yield obtained or protected by the gene(s), the cost per unit output will be fair or they will not pay it in the first place. In reality, they will pay since a protected crop is a value that farmers desire.

Thus, in the changing sense of equity, the public sector is moving to an understanding of the issues and accepts the need to pay for value received. The private sector has generally been aggressive in contractually buying exclusive rights to germplasm of benefit and agreeing to pay for those benefits through royalty compensation. More importantly now, how will the process work? All organizations are more oriented to utilizing material transfer agreements (MTAs) to exchange germplasm in which the limitations to use are spelled out. Development of MTAs, which enable organizations such as the USDA to pass on germplasm and its associated obligatory requirements to others, may be a possible solution to the international germplasm impasse.

However, tracking and monitoring the germplasm community for adherence to the ethical principles of acceptance and compliance with these principles will be important in maintaining such a global arrangement. This approach will have to be accepted by all for it to be effective. The biotechnology industry should foster legitimate exchange mechanisms and attempt to assure that future exchanges are transparent and fair.

The international community should consider some of the following points in establishing a protocol for germplasm exchange and benefits:

- Provide open access to all genetic resources of food and agriculture;
- Engage MTAs to enable research and breeding with the material;
- Enable a brokerage system of recognized third parties to exchange the germplasm and provide annual balance sheets of exchanged germplasm;
- Establish a tracking system and a compensation mechanism to support germplasm conservation activities, when appropriate; and
- Enable a bartering system where access is provided in exchange for training and/or technology.

If there is to be financial compensation where notable genes make contributions to new varieties or hybrids, a scale of declining royalty payments and a fixed time limit needs to be established for each contributing gene. The time limit on a particular variety may be fixed but the genes may be put into other derived varieties. The "profit" or market value of the cumulative sum of all new and old gene contributions could theoretically far exceed any expectations of profitability for any new variety. It must also be noted that value-added germplasm contributions also enter the equation, and that developing countries may now have to pay for that value when in the past, improved germplasm has been available at no cost. The proposed system will develop a bureaucracy and protectionism where there is no winner, particularly for the developing countries least able to afford it. When costs exceed benefits and the system is not working for the countries that need it, it will most likely be scrapped and bilateral conditions under mutually agreed terms will prevail.

References

Conference Report of the Food and Agriculture Organization (FAO) of the United Nations. 1983. International Undertaking on Plant Genetic Resources. Resolution 8/83. Rome

Food and Agriculture Organization (FAO) of the United Nations. 1993. *International Code of Conduct for Plant Germplasm Collecting and Transfer.* Rome

Keystone International Dialogue Series on Plant Genetic Resources. 1991. *Final consensus Report: Global Initiative for the Security and Sustainable Use of Plant Genetic Resources.* Oslo Plenary Session. Keystone, CO

United Nations Environment Program. 1992. *Convention on Biological Diversity.* Nairobi

Intellectual Property Rights: Key to Access or Entry Barrier for Developing Countries

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During the past two decades, improvements in agricultural productivity have been largely based on the introduction of a technology package that includes high-yielding plant varieties, intensive use of chemical fertilizers, herbicides and pesticides, and an abundant supply of water. Despite undeniable success in raising productivity, concerns exist about the environmental sustainability of this model. Use of large amounts of agrochemicals has caused severe soil and water pollution, and the development of strains resistant to pesticides. Water resources are becoming increasingly scarce. Moreover, the genetic base of important high-yielding varieties is increasingly uniform and, as a consequence, they are susceptible to unpredictable outbreaks of disease and to the harmful effects of plant pests. Thus far, however, relatively few farmers in developing countries have had access to this new technology and capital-intensive methods of production.

Nonetheless, the emerging biotechnology revolution is stimulating hope that it will provide the basis for more sustainable agriculture in developing countries. This is because biotechnology today is different from previous agricultural technologies in two ways. First, biotechnology can enhance product quality by improving the characteristics of plants and animals. Second, biotechnology may potentially conserve natural resources and improve environmental quality by using organisms for degradation of toxic chemicals and wastes, fertilizers and soil improvement, and the development of insect- and disease-resistant plant varieties. Many of these applications are, or will soon be, a reality, and they can have far reaching consequences for the solution of important problems of developing countries. It is paradoxical, however, that although developing countries are perhaps the main beneficiaries of agricultural biotechnology, its development is almost exclusively concentrated in highly industrialized countries. That is not surprising in light of the high-level scientific research and the capital it embodies (Solleiro 1995). Moreover, innovation is increasingly controlled by large multinational companies.

In these conditions, it can be expected that the adoption of new biotechnologies by the developing economies will be concentrated in sectors of greatest economic development potential, will increase internal social differences, and will bring greater poverty to small producers and hired personnel.

Faced with this perspective, the only way to confront the above risks while taking advantage of existing opportunities will be by having a greater control over biotechnology in developing countries. That will depend to a great extent on the level of scientific and technological knowledge already attained in this area. But developing countries must not believe that they will be able to go "shopping" to the technology supermarkets of the industrialized countries (Deo 1991). On the contrary, given the barriers erected against the transfer of biotechnology, Third World countries will have to confront the problem of technology diffusion and define policies and practices that will make its use possible.

One of the most important policy instruments for the promotion of biotechnology development deals with intellectual property rights (IPR) protection. Developing countries are increasingly confronted with the fact that a number of bilateral and multilateral initiatives have been taken or are being implemented to "harmonize" intellectual property protection worldwide. "Harmonization" for most if not all countries will mean introducing much stricter intellectual property protection that can have far reaching consequences for the access to and the likelihood of broad diffusion of biotechnologies. This paper presents a brief analysis of the potential consequences to developing countries by the introduction of IPR regulations in accordance with these international trends.

Recent Development in IPR Protection for Plant Biotechnologies

Attempts to strengthen IPR protection regimes have been underway for more than a decade. Initially, the World Intellectual Property Organization (WIPO) served as the main forum. A committee of experts on Biotechnology Property and Industrial Property was established in 1984. Efforts to develop a new treaty on the protection of industrial property have been on-going since 1985. Conventions, however, require wide approval. Industrialized countries have been unsuccessful in getting the higher IPR standards they would like adopted in other countries through WIPO (Belcher and Hawtin 1991).

Some countries, led by the U.S., have subsequently embarked on bilateral negotiations to secure stronger protection for the intellectual property of their nationals. The U.S. has used its General System of Preferences, granting favored-trading status only to those nations that meet rigid IPR protection standards. European countries have had similar commercial policy instruments available to deal with IPR issues.

An extension to these bilateral actions has been the multilateral negotiation of trade-related intellectual property issues under GATT. Indeed, the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement is the most comprehensive international instrument on intellectual property ever negotiated and adopted. The provisions contained in TRIPS constitute minimum standards. Thus, members cannot be obliged to provide a more extensive protection (Correa 1994).

In the area of patent rights, TRIPS contains a number of important provisions. According to article 27.3.b, parties may exclude from patentability:

> plants and animals other than microorganisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, members shall provide for the protection of plant varieties either by patents or by an effective sui *generis* system or by any combination thereof. This provision shall be reviewed four years after the entry into force of the World Trade Organization (WTO) Agreement.

This exception reflects the outstanding differences, even among industrialized countries, on the patenting of plants and animals. The European Economic Community (EEC) proposals in GATT are aimed at maintaining the present position of the European countries which are members of the European Patent Convention. This position has so far been confirmed by the still-under-discussion draft directive on patents relating to biotechnology.

Various elements of article 27.3.b need to be considered (Correa 1994). First, unlike European law and other legislation that followed the same approach, the article refers to "plants and animals" and not to certain classification thereof (*varieties, races or species*)[1]. In the absence of any distinction — and the fact that the second sentence of the same article introduces an exception for one particular classification (plant varieties) — the exclusion is to be interpreted in broad terms as being inclusive of animal and plants — animal races and animal and plant species.

Second, the reference to "essentially biological processes" is limited by the exclusion of "non-biological and microbiological" processes. The concept of microbiological processes as an exception to the exception is present in the European legislation and in the laws of various other countries. Its aim in the TRIPS context is to limit the exclusion of patentability to traditional breeding methods, while preserving the possibility to obtain protection. For example this is evident on developments based on cell manipulation or, with the

[1]The distinction is important. Thus, the prohibition to patent a variety does not prevent European countries to patent a plant, as such. The acceptance of a patent application on the "Harvard mouse" by the European Patent Office was, similarly, based on the judgment that it is not a "race" but a specifically altered animal which is patented.

advances in biotechnology, the transfer of genes. Under the commented text, processes employing microorganisms (such as fermentation) are also patentable, in accordance with current practice in most countries.

More complex and new is the concept of "non-biological process." How a plant or an animal can be produced by a process that is not totally or in part biological? The source and grounds of this text are untraceable. It will probably create more problems than it may solve.

Third, and as an exception to the general authorized exclusion, members must provide protection for "plant varieties" either by patents or by "an effective sui *generis* system or by a combination or both." This obligation is another important basis for the expansion of the scope of intellectual property in a field that most developing countries keep as a part of the "public domain" till now. Although there is flexibility regarding the form of protection, the fact is that all GATT member countries will be bound to protect plant varieties. The flexibility is here, again, a reflection of the lack of consensus among the industrialized countries themselves. While in the U.S. and in Japan a plant variety may be patentable, this is not the case in Europe. The reference to a *sui generis* system suggests the breeder's rights regime. However, the possibility is open to combine the patent system with the breeders' rights regime, or to develop other sui *generis* form of protection. It is unclear why in an instrument aimed at establishing universal standards, the form of protection of plant varieties has not been settled in a more straightforward way, like in other matters of equal or similar importance[2]. In any case, considerable freedom has been left for national legislation to design the system of protection in this area.

Fourth, article 27.3.b is the single provision in the whole TRIPS Agreement that is specifically subject to an early revision — four years after the entry-into-force of the Agreement. This period is even shorter than the transitional period contemplated for developing countries (article 65). This solution suggests how difficult a compromise on the biotechnology-related issues has been and the need for a deeper examination of the matter.

Two other provisions of the TRIPS Agreement should be mentioned here. On the one side — as indicated above — protection of a process is extended to the products directly made with said process (article 28.1.b). On the other, in civil proceedings relating to process patents, the reversal of the burden of proof is established (article 34). This principle may have a substantial impact in the biotechnology field, given the importance of process patents and the often broad claims admitted in this field.

[2]The UPOV (International Union for the Protection of Plant Varieties) convention is not mentioned in the TRIPS draft text nor are breeders rights considered a form of "intellectual property" under the Agreement. Another forgotten modality of protection are the utility models recognized in many developed and developing countries to protect "minor" inventions.

Within this international framework, it is widely accepted that an invention consisting of or using living matter should be protected by IPR. With respect to agricultural biotechnology, the main instruments for protection are patents and plant breeders' rights. Patents are available on processes used to develop modified organisms or to produce biological products.

Patent protection is also available in a number of countries for plants that contain a novel gene. Patents covering genes are not generally confined to the sequence of a gene. The patent typically claims first, a gene or protein, standing alone, corresponding to that sequence; second, a vector or plasmid incorporating the sequence; and, possibly, third, a plant (of a particular range of species) that has been transformed by means of such a vector (and the descendants of the transformed plant). Thus, the patent holder gains effective control over use of the specified gene in genetic engineering (Barton 1994)

In this way a broad scope for protection is granted, which raises concerns about the possibility of extending it to many varieties and even to entire species. This can certainly pose serious threats to breeding activities in developing countries, which have been based rather upon capacities to adapt existing varieties to local conditions. Moreover, scope of protection can be also extended to characteristics of crops, which means that the patent holder could claim a monopoly over any variety expressing the same trait.

Due to these concerns, uncertainty still exists about the final validity of such patents. But, clearly their enforcement would erect important obstacles for biotechnology development and diffusion mainly in developing nations.

On the other hand, Plant Breeders' Rights (PBR) are granted by governments to plant breeders to exclude others from producing or commercializing material of a specific plant variety for, minimally, 15 to 20 years. In order to be eligible for PBR, the variety must be novel, distinct from existing varieties, and uniform and stable in its essential characteristics.

The legislation for both patents and PBR contains provisions for limited unauthorized use of the protected matter. Patent legislation includes a research exemption that allows others to study the protected subject matter without reproducing or multiplying it for commercial purposes. PBR law has important limits designed to facilitate continued improvement of protected varieties. Under the so-called Breeders' Exemption, any protected plant variety can be freely used as plant genetic resource for the purpose of breeding other varieties. Another important feature of PBR is a provision that allows farmers to re-use in their own exploitation the seeds they have obtained, a possibility that patents would exclude.

Demands exist to strengthen the minimum standards for protection of PBR under the International Union for the Protection of Plant Varieties (UPOV). The main change introduced by the 1991 conference included the exclusion of the farmer's privilege. The change also allowed member countries to adopt such provision while allowing the right-holder to prevent such a use on the

grounds that its legitimate interest will be prejudiced. Another important provision is made to prevent the unauthorized exploitation of any variety that is considered to be "essentially derived" from a protected variety. (A variety is considered essentially derived for this purpose when it is derived from the protected variety and retains virtually the entire genetic structure of the protected variety.) In this regard, the revised convention may contribute to dissipating some of the breeders' fears on the eventual impact of the patenting genes that may be incorporated in their protected varieties.

In summary, these new provisions respond to industry's claims for a protection more similar to that conferred under the patent system. Again, these new provisions are meant to protect interests of multinational seed companies and seem to erect new barriers for developing countries' access to agricultural biotechnologies.

Expected Effects of Stronger IPR Protection

As mentioned before, the new international framework for the protection of biotechnologies under IPR has brought some of peace in mind to those who had pressured for change. In a situation where strong IPR protection has been established, foreign biotechnology companies can be expected to be more interested in exporting their modem products, plant varieties and technologies to the country in question. The new framework could also be expected to produce an increase in private research activity, thanks to the economic incentive of the possibility of having a temporary monopoly position granted by different IPR mechanisms. International Property Rights protection can also facilitate the rapid availability of technology and foreign modern varieties, via licensing agreements and other contractual agreements (DG1S 1991).

On the other hand, extension of patent protection to all subsequent generations of a patented living organism by broad claims or stronger PBR protection through the "essentially derived" principle will increase production costs for breeders and may also lead to a control over segments of cultivated crops by IPR holders. This will pose severe difficulties for most plant breeders and small farmers of developing countries to access the benefits of new agricultural biotechnologies.

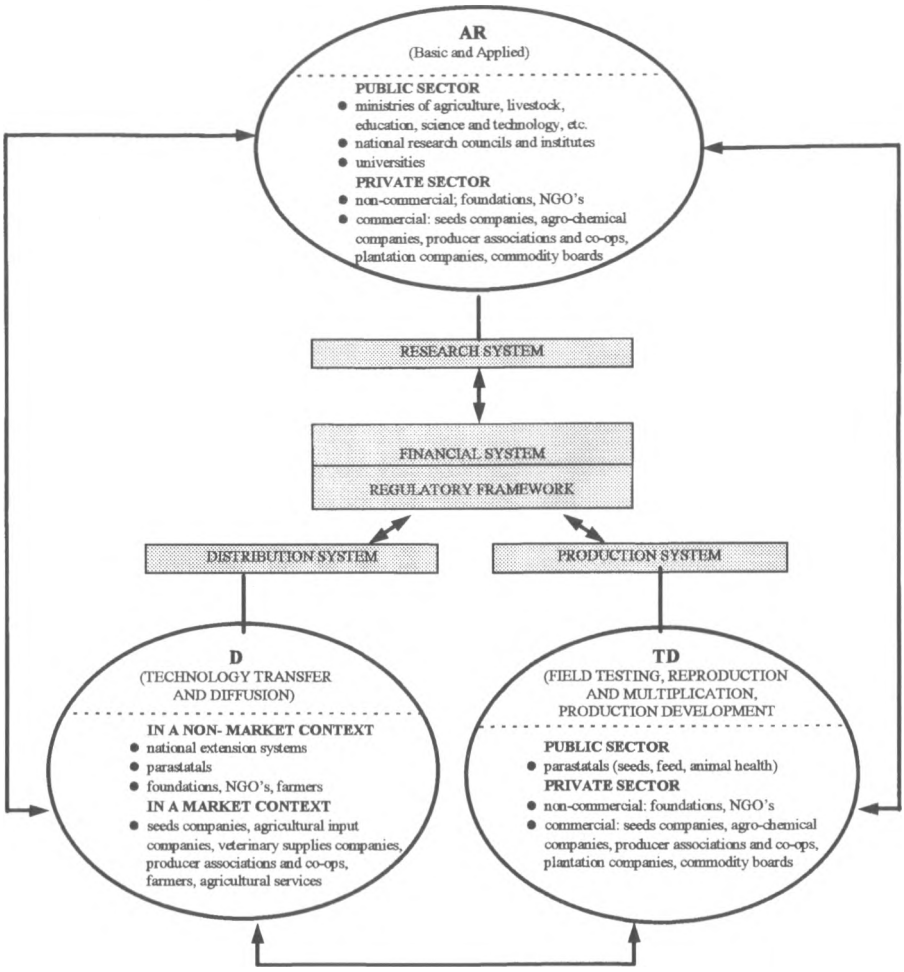
Unfortunately, in most developing countries, lack of a competitive market, limited research facilities and lack of participation of private companies in innovative activities represent serious obstacles to capitalize the benefits of a modern system of IPR protection. Despite the evident progress made by many developing countries to adapt their regulations to TRIPS, it still will be difficult to enforce them. Most countries lack the institutions and personnel for safeguarding IPR. Under present conditions, with a weak innovation system, such protection will mainly benefit large foreign firms wanting to protect an export monopoly and not necessarily interested in manufacturing their biotechnology products in these countries.

If innovation is to be encouraged, IPR protection is an important mechanism. But, it will not work in isolation. New regulations must be conceived within the framework of a national innovation system. This links research, technology development and diffusion as a continuous, interactive process in which local scientific and technological effort is crucial (Brenner and Komen 1994). Figure 1 presents a simplified scheme of a system in which biotechnology and its regulatory framework should be integrated.

FIGURE 1

BIOTECHNOLOGY IN A NATIONAL SYSTEM OF INNOVATION

PUBLIC AND PRIVATE ACTORS AND INSTITUTIONS



Implementation of an innovation-system approach is not only a question of increasing investments in R&D in order to have greater capacity for scientific research. It is also critical to facilitate the adaptation and assimilation of biotechnology developed in other countries. Protection of IPR will then play an important role creating a safe climate for technology transfer. But it has to be integrated to a new biotechnology strategy that should involve closer relationships between science, technology and the market for fostering innovations and their dissemination.

This process for formulating strategies and policies should follow a certain logical order so that the main actors of biotechnology development become committed to certain common objectives and obstacles to technology diffusion can be removed. Thus, the first thing is establishing long-term objectives and priorities, a necessity for making strategic decisions. The second step would involve establishing coherent programs for strengthening the institutional and managerial framework to address these priorities. Sound policy instruments are needed to ensure that researchers, enterprises, Non-Government Organizations and farmers participate in priority projects for introducing biotechnology. Finally, implementation requires continuous monitoring and assessment of achievements and obstacles to maintain quality of technical aspects. Implementation must also include an awareness of the socioeconomic impacts on the introduction of biotechnologies, and make timely corrective actions for attaining general objectives.

References

Barton, J. 1994. *Intellectual Property Protection for Plant Biotechnologies.* Paper presented at the Taller Regional sobre Legislacion y Gestion de la Biotecnologia en America Latina y el Caribe, Bogota. April

Belcher, B. and G. Hawtin. 1991. A *Patent on Life: Ownership of Plant and Animal Research.* International Development Research Centre, Ottawa

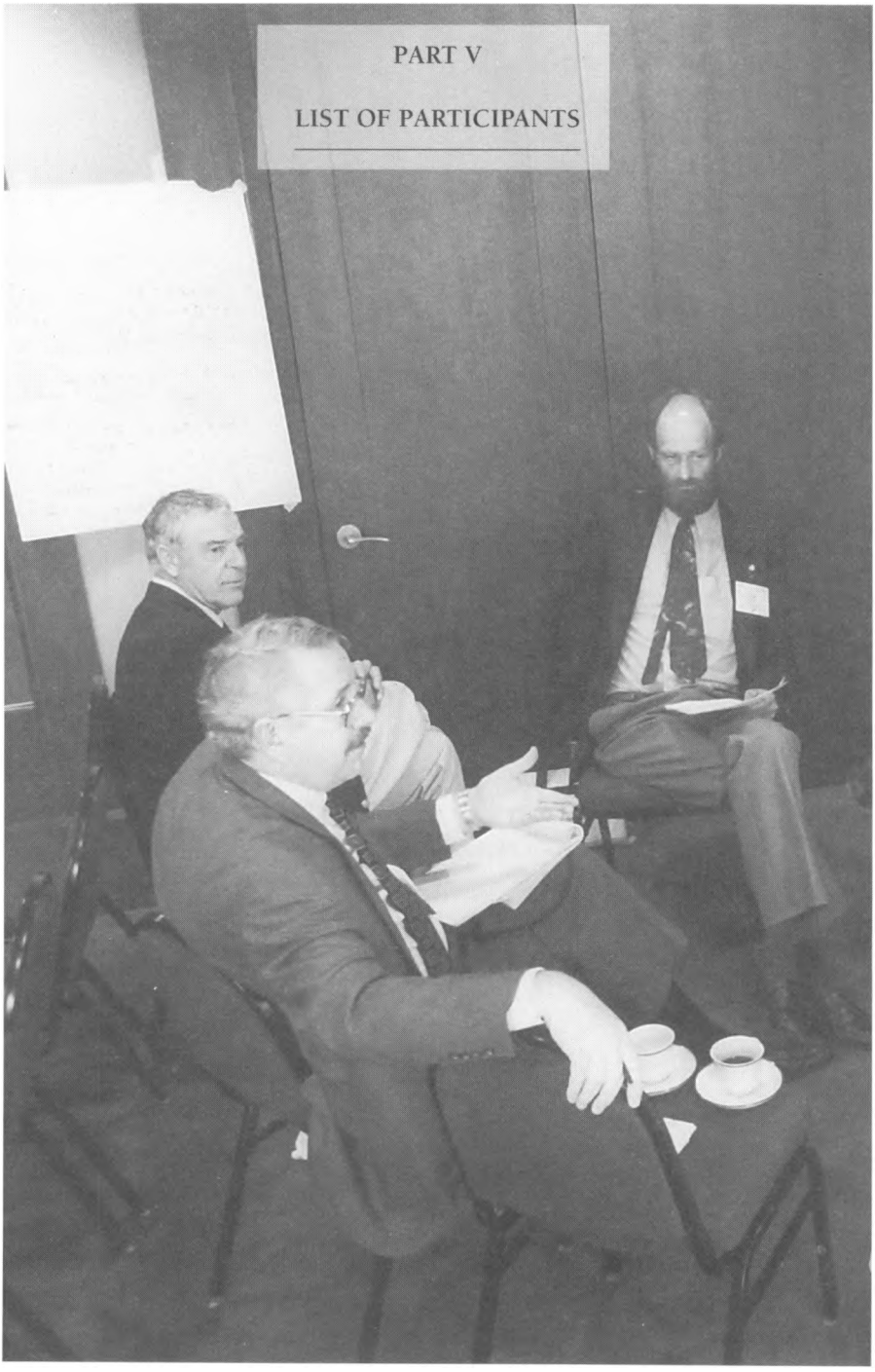
Brenner, C. and J. Komen.1994. *International Initiatives in Biotechnology for Developing Country Agriculture: Promises and Problems.* Technical Papers 100. OECD Development Centre, Paris

Correa, C.M. 1994. *Sovereign and Property Rights Over Plant Genetic Resources.* FAO Commission on Plant Genetic Resources, Background Paper 2. Rome

Deo, S.D. 1991. Implications of Biotechnologies for Third World Agriculture: Lessons of the Past and Prospects. In Sasson, A (coord.), *Biotechnologies in Perspective: Socioeconomic Implications for Developing Countries.* UNESCO, Paris

Direction General of International Cooperation of the Netherlands (DGIS) 1991. *The Impact of Intellectual Property Protection in Biotechnology and Plant Breeding in Developing Countries.* Study committee on biotechnology and intellectual property rights with respect to developing countries. The Netherlands

Solleiro, J.L. 1995. *Biotechnology and Sustainable Agriculture: The Case of Mexico.* Technical Papers 105. OECD Development Centre, Paris



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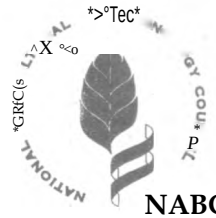

NABC Report 7
Genes for the Future: Discovery, Ownership, Access

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