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23. The Role of Biotechnology Policies and Regulations in Technology Transfer to Developing Countries

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Chapter 23

The Role of Biotechnology Policies and Regulations in Technology Transfer to Developing Countries

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Introduction

In the mid 1980's as agricultural biotechnology began to move toward commercialization in the United States, the development community began to look at the potential application of biotechnology in developing countries. At the time, much was written in the development literature about the potential benefit for food security and, conversely, the potential for economic harm due to replacement of developing country crops. In 1989, the U.S. Agency for International Development (USAID) began to identify areas of agricultural biotechnology that held promise for their client countries and that might be promoted through innovative collaborations with U.S. scientific counterparts. USAID commissioned the National Academy of Science's National Research Council to provide recommendations for a program that would match opportunities in the U.S. and constraints in developing countries.

The resulting report from the National Research Council, Plant Biotechnology Research for Developing Countries (National Research Council 1990), served as the primary base for what became the Agricultural Biotechnology Support Project (ABSP) which was awarded to Michigan State University by USAID in 1991. The project was to be guided by values and principles that reflected a balance of the issues surrounding biotechnology research, both at universities and in the private sector, in the U.S. and USAID's development philosophy:

- Sustainability. The project should fit into the context of agricultural sustainability--that is, an agricultural system that meets rising demands for food at economic, environmental, and other social benefits consistent with improved living conditions.

- Biosafety. Biosafety review and regulation should be internalized in the developing countries themselves as a result of the project.

- Intellectual property rights (IPR). As collaboration between public and private research groups in the United States increases through the course of the project, patent protection of research should be assured so that products can be developed for public benefit.

- Human resource development and networking. Human capacity for biotechnology should be enhanced through doctoral and postdoctoral fellowships or other forms of training.

The rationale for integrating research and technical capacity building with policy work on IPR and biosafety was based on technology transfer trends emerging in the U.S at that time. Recognizing the significant private sector role in biotechnology research, USAID sought to engage the private sector in the development process and to promote both local and international investment in developing countries. This meant addressing IPR both as a means of accessing proprietary technologies from the private sector and in considering the policy environment needed to stimulate private sector investment. Secondly, as a result of the Bayh-Dole Act of 1985, IPR was becoming a more common tool for public universities in the U.S. to promote private sector investment in development and commercialization of research technologies. Thus, in the U.S., linkages were being formed between the public and private sectors, particularly in biotechnology, and managing IPR and biosafety were becoming routine components of university research systems.

In most developing countries, however, agricultural research is conducted almost exclusively within public sector institutes. The private sector in many developing countries is underdeveloped or poorly linked to public research institutions. Additionally, government policies may not encourage investment in research-intensive industries, resulting in agricultural companies that instead focus on publicly available or imported technologies. Thus, in contrast to the trends occurring in the U.S. and other developed countries, relatively few researchers in developing countries understand IPR and biosafety and their relationship to biotechnology, and they may also lack experience in dealing with the private sector. Realizing the positive impact of biotechnology will depend to a large extent on the ability of developing countries to access and/or generate technology suitable to their needs. The first question for USAID was how to promote the access of developing countries to new biotechnologies which were appropriate to address local and regional agricultural constraints, but which were found in the private sector (or held as proprietary information by the public sector) in developed countries. The second question was how to ensure that biotechnology was not only an academic research pursuit but that it could be applied in the field in a manner consistent with USAID's goals of sustainability. This raised the importance of biosafety and risk assessment issues, and the development of local regulatory systems along with the capacity to ensure the safety of biotechnology to both human health and the environment.

The ABSP project thus began in 1991 as a consortium of public sector institutions and private companies in the United States and developing countries of which Michigan State University (MSU) is the lead institution. The project has had successful research and product development collaborations with Costa Rica, Egypt, Morocco, Indonesia, and Kenya focusing on the application of plant biotechnology to production constraints in food crops such as banana, cucurbits, maize, pineapple, potato, sweet potato, and tomato. Private sector partnerships, both formal and informal, have been developed with DNA Plant Technology, Garst Seed Company, Pioneer Hi-Bred, Asgrow Seed Company, Monsanto, and the Biotechnology Industry Organization in the United States; with Fitotek Unggul in Indonesia; and with Agribiotecnología de Costa Rica. In addition to applied research and development, the ABSP project has allocated significant resources to addressing policy issues that affect the adoption of biotechnology, particularly in the

areas of biosafety and intellectual property. The project's use of creative partnerships, between public and private sector laboratories in the US and developing countries, has raised many intellectual property (IP) issues as they relate to the contractual obligations of all parties involved in the project. Also, in moving biotechnology out of the laboratory and into field tests, the project has faced the equal challenge of building local capacity in biosafety to ensure that biotechnology is deployed in an environmentally safe manner.

The following paper provides several examples of how biotechnology policy, both IPR and biosafety, has been part of the ABSP project in practice: where it has been a constraint to the application of technology, and how ABSP has addressed these constraints. Secondly, the paper will examine the ways in which the meaning and significance of both IPR and biosafety have evolved over the course of ABSP's activities as a result of international discussions and agreements. USAID and ABSP initially envisioned biotechnology policy primarily in the context of ways in which technology transfer and access could be encouraged, but international trends have now added trade, economics and politics to the list of challenges facing the development and transfer of agricultural biotechnology to developing countries.

Intellectual Property and Biosafety Constraints in Technology Transfer

Although the ABSP project has focused a significant level of resources both in capacity building, and in the training of developing country personnel in intellectual property and biosafety, these two policy areas remain a significant constraint when transferring technologies to partner countries. IPR issues can be a constraint because individual research institutes find it difficult to move forward in building relationships with partners who hold proprietary technologies unless national policies allow them to do so. This can be a particular problem for public sector institutes, which often do not have the experience or the capacity to negotiate issues of intellectual property with the private sector. Governments generally operate at a snail's pace, and, while the technology may progress rapidly, changes in legislation and development of implementation mechanisms often proceed slowly.

Biosafety considerations also slow the process of technology transfer. In order to transfer any genetically engineered plant materials, in accordance with USAID policy, ABSP must first obtain approval both from USAID's own internal Biosafety Committee, and the appropriate authorities in the partner country. This has so far proved to be a lengthy process in many cases and has considerably delayed transfer of materials. However, it has assisted ABSP in determining the types of training and capacity building that still need to be conducted in order to assist our partner countries in implementing transgenic field trials.

The case studies that follow give an insight into the ways in which IPR and biosafety policies have affected the success of ABSP in transferring technologies through collaborations between public and private institutions in developed and developing countries.

Case Study: CRIFC, Indonesia

An example of a project in which the lack of a national policy framework hindered the transfer of technology is the project established in 1993 through ABSP, between ICI Seeds (now Garst Seed Company) and the Central Research Institute for Food Crops (CRIFC) in Indonesia. This was an applied research project with the goal of transforming maize for resistance to Asian stem borer, an important tropical pest. The initial contract covered technology development, and training at Garst of Indonesian scientists in the techniques of corn transformation, cell culture, insect bioassays, molecular characterization (PCR, ELISA), artificial infestation and field evaluation. Subsequent to the scientists' return to Indonesia, a separate agreement between MSU and CRIFC was initiated to support development of in-country capacity.

At that time, when intellectual property and the products of biotechnology were still in their infancy, CRIFC's experience had been with freely traded products. Indonesia did not have in place patent or plant variety protection laws that protect hybrid seed and transgenic plants. While initially focused on using tropical germplasm, the legal uncertainty surrounding commercialization of maize developed using the biolistic gun required the use of ICI's proprietary technology, which was only successful in transforming a temperate line of maize. This material would have to be backcrossed into tropical maize for development of material suitable for Indonesia. Additionally, the Bt gene, which has been incorporated into the maize, is also proprietary. Indonesia, while making progress in revising its intellectual property laws, still cannot provide adequate legal protection for this material. Unfortunately none of these issues were brought to the table when the initial collaboration was undertaken. In this case, partners expressed reluctance to make commitments until the results of the research were known. The scientific component of the project thus proceeded with great success, but when the scientists returned home, no mechanism existed for them to transfer to their own country the genes and varieties with which they had worked at Garst.

At that time, Indonesia also lacked the appropriate biosafety guidelines or regulations for field testing of genetically engineered plants, and many companies are obviously hesitant to test material in countries without adequate biosafety policies. In recognition of this situation, in 1995, ABSP began providing Indonesia with assistance in developing its national biosafety guidelines. A consultant from the USDA National Biological Impact Assessment Program worked as a special consultant for ABSP and assisted the committee formed by CRIFC in drafting the guidelines. Indonesian experts in each of three research sectors (plants, animals, and microorganisms) were selected as the writing committee with the approval of Indonesia's Ministry of Agriculture. A first draft was produced and entitled "Guidelines for Planned Introductions into the Environment of Organisms Genetically Modified by Recombinant DNA Techniques." In order to improve upon this first draft, CRIFC and ABSP organized a biosafety workshop, held in May 1996, and a total of 45 participants from both the public and private sector attended. Based on the workshop, a new draft was produced, and the guidelines for biosafety were proposed as the basis of a decree from the Minister of Agriculture. A second workshop was then held to finalize the second draft, which was reviewed by Indonesian officials

and the Bureau of Law at the Indonesian Ministry of Agriculture. National guidelines were subsequently passed by ministerial decree on September 2, 1997, and with funding from the World Bank and the Indonesian government, construction of a biosafety containment facility began that year. There are currently several field trials of transgenic crops in the country, all of which have been produced by multinational companies.

The intellectual property rights issues in Indonesia are still largely unresolved and if this situation does not change it will continue to inhibit public sector research institutes from accessing proprietary materials from either the public or private sectors outside the country. ABSP sponsored several individuals from Indonesia to attend workshops and courses in the US on Intellectual Property Rights, and in preparation for drafting Indonesia's plant variety protection law, ABSP sponsored a Plant Variety Protection and Patents Workshop in Jakarta in 1996. The PVP law has now been drafted for some time, and is currently pending the approval of the Indonesian Parliament.

In this example, although USAID and ABSP tried to pre-empt the policy issues that might affect the technology transfer process, additional levels of unforeseen detail were encountered that brought the process to a halt. In the case of Indonesia, the biosafety issues have now largely been overcome, but the questions of IPR have still to be resolved. The transgenic material produced during the project is held in trust, however the research contract with Garst has since expired and due to these constraints was not renewed.

Case Study: AGERI, Egypt

An example of an ABSP project in which policy development more effectively accompanied the science, is the collaboration between the Agricultural Genetic Engineering Research Institute (AGERI) in Egypt and Pioneer Hi-Bred International, a private seed company in the US. The project goal was to develop Bt transgenic maize germplasm with resistance to corn borers endemic to the Middle East, and also included the training of Egyptian scientists. The overall collaboration between ABSP and AGERI began earlier, in 1992, with the aim of producing a range of improved crops (e.g. tomato, maize, cucurbits, potatoes) with pest and disease resistance. Capacity building activities to promote biotechnology policies began at that time, thus laying a good foundation for the research projects that followed.

During the development and initial phases of the projects, ABSP provided varied support and training to Egypt on several levels to aid in the establishment of policies that would facilitate the process of technology transfer. These activities included sending individual scientists on biosafety training workshops, followed up with a two-week internship program in biosafety held in August 1996 in cooperation with the Information Systems for Biotechnology project at Virginia. On a larger scale, ABSP also organized a regional biosafety workshop in Cairo, in 1994, which was attended by over 100 biosafety, science and regulatory personnel from Egypt and other countries in Africa and the Middle East.

Through support from USAID/Cairo and the World Bank, the ABSP/AGERI project, in cooperation with the University of Arizona, managed the construction of a modern biocontainment greenhouse facility at AGERI in Cairo. The greenhouses were completed and inspected by the U.S. Department of Agriculture in 1995, and AGERI scientists are now using this facility for greenhouse testing of transgenic plant materials developed in the ABSP projects. Until 1995, existing regulations in Egypt did not include guidelines for handling transgenic materials under contained conditions, nor did they cover the release genetically engineered organisms into the environment. As the primary institute that dealt with agricultural biotechnology in Egypt, AGERI was in a good position to advise the Egyptian government on policy issues, and was subsequently able to influence the Egyptian government in moving forward to build a national biosafety policy to regulate such activities. They first gathered information from other countries regarding their regulations, guidelines, and system design and then drafted regulations and guidelines adapted to the Egyptian condition, which were revised and approved by governmental authorities in 1995. AGERI scientists, with training received through support of ABSP, were instrumental in drafting these regulations. By ministerial decree the Egyptian National Biosafety Committee (NBC) was also established in 1995, and several field trials of transgenic crops are now being carried out in the country. These trials include material developed under other ABSP research projects, for example potatoes with engineered resistance to the potato tuber moth, in addition to transgenic crops produced by private companies. The ABSP transgenic potatoes were one of the first products assessed by the new national biosafety committee in Egypt, and the process was relatively quick and straightforward because of the effective system that was already in place.

ABSP addressed the Intellectual Property Rights issues in Egypt in a similar way to the biosafety issues - that is, with a combination of individual training of scientists and those directly involved in developing transgenic materials, together with broader workshops that included policy makers and government officials. ABSP used the services of a consultant for intellectual property rights, patents, and licensing from Stanford Law School to help addressed the licensing and intellectual property problems that arose in connection with the transfer and ownership of technologies developed by the project. A major outcome of these workshops was the initiation of communication between scientists working in biotechnology programs and legislators and policy makers in Egypt, however their national IP legislation still does not meet the general requirements of TRIPS.

In the specific example of the relationship between AGERI, an Egyptian public sector institution, and Pioneer, a U.S. private company, the IP issues were crucial to the success of the project. ABSP brought assurances of confidentiality that encouraged Pioneer, and insisted that intellectual property protections would have to be in place before research was begun. The Director of AGERI also announced to his entire work group that respect for intellectual property was imperative to the project. Without such assurances, Pioneer would not likely have become a collaborator. The importance of co-development of technology as opposed to technology transfer is especially pertinent in the case of Pioneer's relationship with AGERI. IP played an additional role in actually

encouraging the collaboration - AGERI had isolated a number of strains of Bacillus thuringiensis that had pesticidal activity of interest to a private-sector company, and they were able to bring these to the relationship as a 'bargaining chip'. AGERI also has a state-of-the-art biosafety facility and a cadre of trained scientists. In turn, Pioneer came to the table with technology as well as with marketing, regulatory, and legal expertise of value to AGERI. Finally, ABSP offered funding that would defray some of Pioneer's costs in training AGERI scientists, and without which Pioneer might not have entered into such a collaboration. There is no doubt in this case that the successful collaboration between AGERI and Pioneer supports ABSP's experience that co-development of technology provides important incentives on all sides to move a project forward.

In summary, the success of the projects in Egypt has largely been due to the joint emphasis that was placed in the very early stages on policy development activities being carried out simultaneously with the research. If research had been the only activity, it is likely that none of the products would yet be tested in the field. It is also our belief that policy development is itself encouraged by the research efforts. If the policy makers can see that there might be some concrete benefit to having the appropriate policies in place e.g. the availability of a pest resistant potato which might overcome serious production constraints in Egypt, there is more incentive to push legislation through the system.

Case Study 3: Monsanto and Sweetpotato in Kenya

An informal arrangement involving ABSP illustrates another example of research and policy collaboration, between Monsanto and the Kenyan Agricultural Research Institute (KARI). Monsanto previously had been awarded a grant from the USAID Office of Agriculture to assist KARI in producing genetically engineered sweet potato for resistance to Feathery Mottle Virus, a virus that can acts synergistically with others to decrease yields of sweet potato from 20 to 80%. Transgenic lines of sweet potato containing the SPFMV coat protein were developed, and Monsanto donated this technology royalty-free for use in sweet potatoes in Africa. This effectively removed any constraints due to intellectual property issues, and biosafety was the major constraint to transfer of the technology to Kenya.

In this example, because ABSP had identified Kenya as a focus country for Africa and identified sweet potato as an important crop for both Kenya and Indonesia, it teamed up informally with Monsanto to help develop the procedures and assist in the transfer of materials for testing in Kenya. ABSP also supplied Monsanto with information about technology transfer to developing countries. In the process, ABSP supported a postdoctoral researcher at Monsanto and short-term visits of Kenyan and Indonesian scientists to Monsanto. It also funded a biosafety consultant to assist Kenyan scientists in developing a proposal for review by the Kenyan Biosafety Committee and USAID's Biosafety Committee and supported a direct subagreement with KARI to assist in in-country capacity development and technology transfer. At the end of the initial grant, Monsanto continued to support the project from its own resources and from funds provided by several other organizations. These biosafety capacity building activities of

ABSP and other organizations, notably the International Service for the Acquisition of Agri-biotech Applications (ISAAA) have likely contributed substantially to Kenya's leading position in sub-Saharan Africa in moving forward in the application of biotechnology.

The transgenic sweet potatoes were the first product to be reviewed by the Kenyan National Biosafety Committee. This review is now complete and field trials are due to be planted in late 1999.

IPR and Biosafety: Trade, Economics and Politics

Since the design of ABSP, the global dialog on genetic resources and biotechnology has expanded, notably with greater participation in the debate by developing countries. This extensive dialog is changing the environment in which development programs such as ABSP work. Several key international agreements and ongoing international discussions have shaped the biotechnology and development agenda, broadening it beyond a focus on cooperative research and technical capacity building to include trade and larger political, cultural and economic issues. These changes have increased the priority that many developing countries place on capacity building in agricultural IPR and biosafety and have challenged development programs to recognize the broader political and economic significance of these issues beyond technology transfer and technology access.

Perhaps the most significant international agreement to reshape the environment for international biotechnology development is the Convention on Biological Diversity (CBD) which entered into force in 1994. The CBD represents an important step in biodiversity conservation for the environmental community. It also represents an important political expression for those who felt that the system of free access to genetic resources and the increasing extension of IPR to genetic resources were unfair to developing countries, benefiting primarily the commercial sector of developed countries (Whitmeyer 1997). In most concrete terms, the CBD altered the global system of free access to genetic resources by allowing countries to exert sovereignty over their genetic resources and to control access by these researchers and commercial firms alike. More importantly, though, the CBD highlighted the more politics of equity between developed and developing countries in realizing the economic benefits of biodiversity, including, specifically, those derived from biotechnology. It did so in two ways: through an emphasis in a number of articles on the need for increased technology transfer and capacity building in biotechnology, and through references to the need to consider the potentially disadvantageous position of developing countries with respect to IPR (UNEP/CBD, 1994). The latter is dealt with in the context of both concessional terms for the use of proprietary technology by developing countries and in the equitable sharing of the economic benefits derived from IPR.

For international development programs such as ABSP, the impact of the CBD has been in some cases specific, such as increasing the emphasis developing countries

place on legal training, but more subtly has been to politicize the environment in which developing countries and development organizations approach biotechnology capacity building. In the first five or so years of the ABSP project, it was primarily USAID's program design - incorporating IPR alongside research as a means of promoting technology transfer - that framed IPR capacity building activities. Since the CBD, and the WTO agreement as noted below, developing countries have increasingly approached IPR from the perspective of equity: both seeking capacity building in IPR to increase their share of economic benefits derived from biotechnology, and, conversely, to question the fundamental application of IPR to agriculture and biotechnology from a cultural perspective. The overarching political and economic principles that the CBD highlighted with respect to IPR have shown up, for example, in a recent workshop ABSP held in East Africa where the term biopiracy was raised on more than one occasion. It has been important for ABSP and USAID to recognize the new environment, but it has been equally important to move the depth of discussion with developing country partners beyond the rhetorical level. Researchers in developing countries will likely encounter IPR in collaborating with public and private institutions in developed countries regardless of the policy decisions those countries take toward IPR protection nationally. Further, as countries move towards development of policies in line with the CBD it will be important that issues such as IPR, and biosafety as discussed below, reflect cross sectoral discussion among agricultural, scientific, environmental, legal, and trade policy makers. Because of their broader impact on agriculture and research, it is disconcerting that such discussions are not generally the source of national positions or policy decisions. Recognizing that biotechnology is not just a scientific issue in the international community, it is none-the-less important that technical capacity building in biotechnology, IPR, or biosafety feed into the policy making process.

A second international agreement which deals with agricultural IPR is the World Trade Organization's Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS). Also adopted in 1994, the TRIPS agreement set forth a requirement for WTO members to provide IPR protection for plant varieties through patents or by an effective sui generis system (Leskein and Flitner 1997). TRIPS allows countries some flexibility in the precise form and the extent of protection. None the less, it promotes the fundamental idea of extending IPR to agricultural genetic resources. The response by developing countries to the TRIPS agreement has been from two directions. One, countries interested in both the potential benefit of crop-related IPR policies and in meeting the WTO deadline for implementation of the TRIPS agreement, have sought assistance from programs such as ABSP in developing and implementing national systems of plant variety protection (PVP) such as that outlined by the International Union for the Protection of New Plant Varieties (UPOV). This has been the case with ABSP's work in Morocco and more recently in East Africa. Conversely, much has been written and expressed by developing country representatives critiquing the benefit of the TRIPS agreement for developing countries and questioning the consistency of TRIPS, and UPOV, with the CBD (Ekpere 1999). While it is not clear that legal conflicts between the CBD and TRIPS do actually exist (UNEP/CBD 1996), the political significance of such a debate carries into international biotechnology development programs. As with the CBD, the challenge is to recognize the diverse perspectives, but to move beyond

solely the political and into the specific legal and scientific issues surrounding PVP. For countries to pursue their options under TRIPS for sui generis systems of PVP, an understanding of the legal, economic, and scientific costs and benefits of policy options will be essential. Further, the implementation of PVP will likely be the responsibility of agricultural rather than trade or legal ministries. Thus, WTO compliance, like the CBD, should involve dialog between agricultural and trade policy makers.

Finally, the Biosafety Protocol to the CBD has been under negotiation for the last several years and reached a dramatic point in February of this year with the failure to reach international consensus at the final negotiating session in Cartagena. The Biosafety Protocol seeks to establish international regulatory procedures for the transboundary movement of the products of biotechnology as a means of mitigating potential negative effects of biotechnology on biodiversity. Like the parent agreement, the CBD, the Biosafety Protocol goes beyond solely environmental conservation to address issues of technology transfer and capacity building for developing countries. It also shares the CBD's equity agenda of restricting trade and the economic pursuit of biotechnology development. The CBD provided for restrictions on access to genetic resources as a means of partially addressing the equity of benefits derived from commercial biotechnology, but in so doing also affected non-profit public research. Similarly, the Biosafety Protocol, while largely focused on commercial trade, will also impact technology transfer and cooperative research undertaken by international development programs. In practical terms, it remains questionable whether the Biosafety Protocol will unintentionally create significant barriers to non-profit oriented technology cooperation and capacity building. While still under negotiation, an impact of the Protocol negotiations is already seen in the high priority developing countries now place on biosafety over any other area of biotechnology capacity needs (Cohen et al. 1998). Further, given the strong concerns expressed by developing countries in the Protocol negotiations, USAID has reviewed its internal biosafety procedures that govern biotechnology programs including ABSP to ensure that the procedures address both their concerns and USAID's liability.

Conclusions

In 1989 when ABSP was designed, the program's priorities and design were shaped primarily by the issues surrounding agricultural biotechnology development in the United States. In the intervening years, the international community has focused greater attention on biotechnology, resulting in several international agreements that deal in part with IPR and biosafety as it relates to biotechnology. While in light of these agreements the general design of ABSP remains sound, the priority of IPR and biosafety compared to technical and scientific capacity building has increased and the context in which these issues are addressed has changed dramatically. IPR and biosafety are not restricted to technology transfer and access, but surrounded by underlying political, economic and trade concerns. Importantly, in addition to recognizing these broader implications, the sequence in which ABSP approaches these policy issues is changing. As the previous examples illustrate, the program has generally pursued IPR and biosafety in the context of an ongoing collaborative research program. Thus, policy development went along

with, and indeed generally moved more slowly than, technical training and co-development of specific biotechnology applications of interest to the country. This approach had benefits in providing a technical underpinning to policy development and a hands-on understanding of the impact of policy on biotechnology research. In the wake of international agreements such as the CBD and TRIPS, developing countries are placing more emphasis on the need to establish policy and regulatory frameworks in the short term, perhaps before biotechnology research or a technical understanding of biotechnology is in place at the national level. These changes in the international environment are reshaping how we engage in biotechnology programs.

Endnote

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