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on

PUBLIC-PRIVATE PARTNERSHIP IN AGRICULTURAL BIOTECHNOLOGY

by

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Contributions: Dr. Khush alongwith his team has developed over 300 new rice varieties, including IR8, IR36, IR64 and IR72, which triggered the Green Revolution in Asia in the 1960s. In 1976, Dr. Khush developed IR36, called "the miracle rice" that has since become one of the world's most widely grown food crop varieties, which has added about five million tonnes of rice annually to Asia's food production.

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Scientific advances in plant breeding led to "Green Revolution" regarded as the most important agricultural achievement of humankind. This revolution targeted staple cereal crops particularly rice and wheat with staggering results. Food grain production in India doubled in a short span of 25 years between 1970 and 1995. The credit for this achievement goes to Indian scientists and policy makers. While we should be proud of these achievements, we should not become complacent. Our population is increasing at the rate of 1.9% per year and we are adding 19 to 20 million new mouths to feed every year. Moreover, as the living standards of our people improve, they shift from low value to high value foods such as eggs, milk and meat. To meet this demand, more cereals are needed as livestock feed. It takes 2,4 and 8 kilograms of grain to produce 1 kg of poultry, pork and beef respectively. This increase in demand for livestock products implies increased demand for cereal grains as livestock feed. According to various estimates, we will have to increase food grain production by 50% in 2030 when our population is likely to stabilize.

Compounding this food grain production scenario is the realization that additional food grains will have to be produced from less land, with less water, less labor and less chemicals without degrading the fragile resource base. Agricultural research and technological improvements will continue to be a pre-requisite for increasing crop productivity. Major emphasis will continue to be on development of crop varieties with higher yield potential, durable resistance to diseases and insect, tolerance to abiotic stresses, and more nutritious grains. Time tested methods of classical breeding such as hybridization and selection, ideotype breeding and hybrid variety development will continue to be used but tools of biotechnology will play increasingly important role in crop improvement. Amongst the frontier technologies for crop improvement, molecular marker aided selection and genetic engineering have captured the imagination of crop scientists and policy makers alike. Construction of dense molecular genetic maps of major food crops has ushered in the era of molecular markers which are being employed for moving genes form one varietal background to the other and for pyramiding several genes for the same trait such as disease and insect resistance through molecular marker aided selection (MAS). Genetic engineering or recombinant DNA technology has offered exciting opportunities to introduce cloned genes from unrelated sources into crop varieties for increasing yield potential, disease and insect resistance, tolerance to abiotic stresses and for introducing novel grain quality traits.

The immediate potential benefits from the use of biotechnology tools include; (1) increased food supply for consumption, (2) increased farm input for cash, (3) reduced cost per unit of output, (4) employment generation for food processing, (5) growth of non-farm local economies, and (6) poverty alleviation, particularly for rural poor.

Status of biotechnology in developing countries

Biotechnology research, currently being carried out in private as well as public organizations is broadly divided into five categories.

1. Large global private sector companies such as Monsanto, Syngenta Bayer, and Du Pont, etc.
2. Public sector research organizations in National Agricultural Research Systems (NARS) including universities.
3. The International Agricultural Research Centers (IARCs) of

the Consultative Group on International Agricultural Research (CGIAR)

4. Public research organizations including universities in industrialized countries.
5. Various other international initiatives funded by donors and non-profit foundations of industrialized countries.

There is little doubt that globally, the private sector is the major player in biotechnology research. According to one estimate, the major life science companies invested some US$2.6 billion in agricultural research and development in 1998. Only a small proportion of this private R&D is directed at developing countries, most of this occurring through direct investment by the global life science companies through alliances between local and global companies.

The public sector finances, around 90% of total agricultural research in developing countries, compared to about 50% in industrialized countries.

There is huge diversity among NARS in developing countries with respect to their capacity in agricultural biotechnology R and D. Byerlie and Fischer have divided the developing country NARS into three groups according to their biotechnology research capacity.

- Type 1 NARS have strong capacity in molecular biology to develop new tools and products for their own specific needs. India, China, Mexico and Brazil are in this category.
- Type 2 NARS have considerable capacity to borrow and apply molecular tools, e.g., molecular markers and transformation. Thailand, Philippines, Indonesia, Colombia, Argentina and Kenya fall into this category.
- Type 3 NARS have a very fragile capacity to borrow and apply molecular tools developed elsewhere. Several NARS in Asia

(Laos, Cambodia, and Myanmar) and most in Africa fall into his category.

Type 1 and 2 NARS have instituted a regulatory framework for the testing of transgenic crops and for protecting intellectual property (IP). Most type 3 NARS have no regulatory framework in place even to import and test transgenic products.

Accessing Proprietary Technologies

Several mechanisms for accessing proprietary technologies by the public sector from the private sector and sometimes other public sector organizations are available. These include business and legal options to gain access to proprietary technologies such as confidential agreements, material transfer agreements, licensing, purchase, and joint ventures. Up to now, there is limited experience in developing countries with these various types of agreements. Some of the options are as follows:

Unilaterally accessing technologies

One option for the public sector is to unilaterally access a tool or technology, especially those technologies that can be easily copied such as a specific gene from a transgenic variety without seeking permission of the owner. This is legal if the patent for the technology has not been lodged in the country where the technology is to be used and if the product is not exported to a country, where there is a protection on the invention. This is most likely to be the case with type 3 NARS. However, many critical tools and products of biotechnology have been widely patented in many countries especially in type 1 and type 2 NARS.

A recent review of the proprietary technologies for golden rice illustrates the patterns of protection. There were 44 potential patents related to this rice in USA but the number of patents in different relevant countries varies form none to 11. All type 1 NARS would face restriction, but there is no clear relationship between the number of potential patents and importance of rice and strength of public sector research programs. For example, no patents have been taken out or filed in Thailand, a type 2 NAR, while patents have been taken out or filed for several of the technology components in countries with little capacity in biotechnology (e.g. in some African countries).

Purchasing the Technology

Proprietary technologies can be bought by the public sector for use in developing countries. For example, a consortium of public-sector institutes in Asia led by the International Rice Research Institute (IRRI) purchased the right to *Bt* gene owned by Planttech, a Japanese company. The consortium then decides whether to make the materials public property or allow others to use the technology, subject to royalty payment. There are over 50 instances where Latin American NARS have purchased proprietary biotechnology tools and products.

A variant of this approach would be to contract with the private sector, through competitive bidding, to develop a specific tool, but with public sector retaining ownership of the product. This is most appropriate where the expertise exists in the private sector to adapt a product to a specific situation with considerable certainty.

Material transfer and licensing agreements

Material transfer agreements (MTAs) are often used to define conditions for the transfer of research materials and tools for use in research only, leaving the need to develop a license for commercial use of final technologies to a later stage. Public research organizations favor MTAs that define "front-end decision" about priorities and resource contributions. Upfront costs are minimal and risks are reduced because the negotiation for the use value occurs after the values of the product, if any, is known. However, this practice can also weaken the negotiation position of licensing for the use phase, since the greater the success of the research greater the value of the technology and therefore greater the expectation of the return by the owner. In some cases, the flow of research products to users has slowed after considerable investment in product development because of the failure to reach agreement about commercialization and royalty sharing.

Opportunities for Public-Private Partnership

There is no denying the fact that public sector is in a unique position to play a key role in biotechnology R and D in developing countries, but working alone public sector will make a slow progress. Therefore, public-private partnership is highly desirable for the developing countries to harness the benefits of biotechnology. There is no greater incentive for collaboration between the public sector in agricultural research than the enormous challenge posed by global food security. A large investment of the private sector in biotechnology has clearly demonstrated the need for and significant advantage associated with collaboration between the public and private sector in agriculture.

The public sector organizations invest in agricultural research to maximize societal benefits and private firms need to earn profits in order to give good returns to their share holders. Both public and private sectors have complementary assets, which are a magnet for collaboration. Public sector assets include germplasm, evaluation networks, expertise in breeding, familiarity with local growing conditions and access to seed delivery system, relationships with extension organizations and in case of International Agricultural Research Centers, reputation and goodwill they enjoy with NARS. Global life science companies have assets in the form of biotechnology tools, genes, promoters, markers, technical knowhow, financial resources, and skills in dealing with regularity agencies.

The goal of partnerships is not to transform public sector institutions into private companies. The private sector is unlikely to replace the role of the public sector in research or in facilitating broad applications of biotechnology in developing countries. Rather the role of the public sector will remain vital, as the private sector is unlikely to deliver biotechnology applications for many crops grown by the poor farmers and orphan crops and to address all biotic and abiotic production constraints important in developing countries. It is the responsibility of public sector to fill these gaps. Moreover, the public sector will continue to provide a critical role in addressing broad policy issues, and guiding programs that optimize public benefits from technological innovations in agriculture.

Some Examples of Public Private Sector Partnerships

There are several successful examples of public-private partnerships that have facilitated access to biotechnology and development of improved crop varieties for developing countries. Such partnerships have been brokered by nonprofit organizations with a mandate to help the transfer of technologies to developing countries.

Components of such partnerships include: (1) outright donation of technology by private firms to national public research institutions, (2) institution capacity building in biotechnology tools, regulatory procedures and IPR, and (3) information and knowledge sharing. In some partnerships, donors of technology also benefit.

Collaboration for Resistance to Insects in Corn

Potentially novel strains of *Bacillus thuringiensis* (BT) were characterized by the Agricultural Genetic Engineering Institute (AGERI) in Egypt in collaboration with US-based Pioneer Hi_Bred company. *Bt* gene isolated from these strains was introduced into locally adapted varieties of corn to develop insect resistance in those varieties. The collaboration involved training of AGERI scientists for characterizing BT and maize transformation, while Pioneer was granted access to evaluate novel BT proteins and genes patented by AGERI. The project was brokered and supported by the Agricultural Biotechnology Support Program (ABSP) of the US Agency for International Development (USAID) based at the Michigan State University, USA.

A particularly significant aspect of the collaboration was that the ownership of IPR related to these Bt strains belonged to public sector (AGERI) and was made available to Pioneer under the term of a contractual agreement. AGERI is pursuing commercialization of BT maize varieties in Egypt while Pioneer used the license in USA.

In Indonesia, ABSP supported collaboration between ICI seeds (now Syngenta) and the Central Research Institute for Food Crops (CRIFC). The focus of the project was development of tropical maize varieties resistant to Asian corn borer. It included training of CRIFC scientist in the use of transformation technologies. The experience of ABSP highlighted the challenges faced by public-private sector partnerships. The most significant constraint encountered was related to IPR, due both to lack of awareness and management capacity in public institutions, as well as differences in the extent of IPR protection provided by national laws. Despite capacity building efforts to address this issue, due to absence of IPR protection, the CRIFC/ICI project ran into difficulties at the stage of negotiating technology transfer agreement and the project between CRIFC and ICI could not be implemented. Many of the public sector research institutions in developing country NARS especially in types 2 and 3 NARS are not well versed in negotiating with public sector. Moreover, companies are not used to slow bureaucratic process and go©Pvernment requirements. Type I NARS have developed sufficient capacity in handling IPR and Type 2 and 3 NARs should enhance their capacity in this vital area if they have to benefit from public-private partnership.

Papaya Biotechnology Network

The importance of papaya in developing countries in terms of daily consumption is next only to bananas in Southeast Asia. Unfortunately, papaya is affected by several diseases and pests, the most important and widespread of which is ringspot virus (PRSV), which drastically reduces papaya yields and has a devastating effect upon the livelihood of subsistence farmers.

International Service for the Acquisition of Agri-Biotech Applications (ISAAA) developed and brokered a project with support from both the public and private sectors to develop ringspot resistant papayas. Monsanto and scientists of the University of Hawaii are now collaborating with the network to develop PRSV-resistant papaya, while the former Zeneca Plant Science (now Syngenta) and the University of Nottingham are sharing their technology and expertise to develop delayed ripening papaya. The network includes national scientists from Indonesia, Malaysia, Philippines, Thailand and Vietnam. The program seeks to enhance income, food production, nutrition and productivity for resource poor farmers. As a part of the project, scientists from the five countries have been trained in transformation technology, biosafety, food safety and IPR management through workshops, courses and internships. Malaysia has made good progress in terms of the development of delayed ripening papaya and is conducting its first contained field trial. Thailand has already developed and field-tested several promising PRSV-resistant papayas. However, bureaucratic processes and stringent government requirements for biotechnology work, especially for field testing, have consistently delayed progress of the network. Other problems include a lack of skilled personnel and national capacity and chronic inadequacy in public sector research funding in developing county partners.

Virus Resistant Sweet Potato in Kenya

Sweet potato is an important food security crop in Africa especially during the maize crop failure. It yields higher amounts of food energy and micronutrients per unit area than any other crop. The production of sweet potato is however constrained by a number of factors, in particular the disease, caused by sweet potato feathery mottle virus (SPFMV). It may cause up to 80% yield loss in susceptible varieties in many parts of Africa.

In 1991, ISAAA developed and financially brokered a research partnership for developing SPFMV resistant sweet potato through biotechnological approaches. The initial partnership involved the Kenya Agricultural Research Institute (KARI), Monsanto, USAID's ABSP and the Mid American Consortium. Monsanto donated through a royalty free license, virus resistance technology for application to sweet potato. Through this partnership, genetically modified (GM) SPFMV-resistant sweet potatoes have been developed using Kenyan varieties. Besides, several Kenyan scientists have been trained both in the USA and in Kenya on various aspects of transformation, the establishment of biosafety structures, preparation and submission of biosafety permit application, laboratory and field evaluation of GM crops, IPR protection and technology transfer mechanisms. The GM sweet potatoes are now being tested on station trials in four KARI centers in Kenya.

Super Sorghum

Sorghum is the dietary staple for more than half billion people. It is the sixth most widely planted crop in the world grown on 40 million hectares and currently produces 60 million tons grain each year. It is the staple food in many African countries. It is low in protein quality due to its low content of essential amino acids such as lysine. The reliance on sorghum as dietary staple results in problems associated with malnutrition especially in children. In view of its importance in meeting nutritional needs of millions of people and limitations of breeding to develop nutritionally fortified varieties using conventional methods, modern genetic engineering techniques have to be utilized to develop biofortified sorghum cultivars that are high yielding, rich in essential amino acids and acceptable to farmers and consumers. Africa Biofortified Sorghum (ABS) project aims to accomplish that. Project consortium is a needs driven, Africa initiative and it brings together nine globally respected institutions.

Africa Agricultural Technology Foundation (AATF) is the lead agency. Included in the consortium are public institutions as well as a private company. ICRISAT a CGIAR institute is providing germplasm and transformation technology. Pioneer DuPont has donated intellectual property rights, materials and expertise for creating sorghum with improved nutritional value for human consumption. The initial donation is transgenic biofortified sorghum that contains 50% more lysine compared to traditional sorghum. Lysine is an amino acid and a key component of protein.

Golden Rice Humanitarian Board

Golden rice is an excellent example of the potentials and hurdles of public private partnership. At least 400 million of the world's population has vitamin A deficiency and of that, 100 million are children. Every year, at least half a million children go partially or totally blind because of vitamin A deficiency and are at increased risk of respiratory diseases and diarrhea. Rice grains do not contain betacarotene, the precursor of vitamin A. Therefore, poor people who derive vast majority of their caloric requirements suffer from vitamin A deficiency. A research team led by Swiss Scientist, Ingo Potrykus, developed GM rice by introducing three genes; two form a plant (daffodil) and one from a bacterium (*Erwinia uredovara*) which produces betacarotene . Due to the presence of betacarotene, the grains are yellowish in color hence the name "golden rice". Dr. Potrykus wanted to transfer the golden rice materials to developing countries for further breeding to introduce the trait in local varieties consumed by the poor people. However, Potrykus team had to take care of IP used in the development of golden rice. A survey uncovered 70 patents belonging to 32 different companies and universities embedded in golden rice. This clearly presented a major challenge to inventors who wanted their invention to reach poor farmers free of charge and without restrictions. After lengthy negotiations, arrangements were made to enable the delivery of this technology for humanitarian purposes. First, the inventors assigned all their rights to a company call Greenovation that licensed to Zeneca (now Syngenta) all rights to golden rice related inventions. Syngenta arranged for further technology licenses to be granted for humanitarian use in connection with Syngenta's Humanitarian license terms. Syngenta had to secure rights from several companies such as Bayer, Mogen, Novartis, Monsanto, Zeneca and a Japanese company. All of these licenses are for defined humanitarian use. Syngenta then granted back a license with rights to sublicense for humanitarian use to the inventors that retained all commercial rights. Syngenta also agreed to license further improvements and share regulatory data as well. The rights are transferred to developing countries, and institutions that assist them such as IRRI by inventors through a sublicense with or without right to sublicense. A sublicense with the right to sublicense has been granted to IRRI. No materials may be passed to researchers/ institutions that have not executed a valid license. Humanitarian use has been defined as use in developing countries (according to FAO definition), by resource poor farmers who make less than US$10.0000 per year, leaving the company free to explore commercial prospects for the technology. To date licenses have been given to six major rice growing countries namely Philippines, India, China, Bangladesh, Vietnam and Indonesia. It represents an excellent example of a public-private partnership.

A major hurdle remains before this rice will reach subsistence farmers. The trait needs to be transferred to many locally adapted rice varieties in rice growing countries. Careful need assessment and analysis of pros and cons of alternative measures, bioavailability, food safety, biosafety and environmental and economic assessments followed by field trials are needed. A golden rice humanitarian board has been set up to provide advice and support throughout this process.

Rice Functional Genomics

Rice is the most important food crop for half the world's population. In Asia, the yield gains in rice have been crucial in keeping with growing population. Since 1962, population in Asia has more than doubled from 1.6 to 3.7 billion. Rice production has grown by 170%, whereas the land area planted to rice increased only marginally (21%) during the same period. The increased production efficiency has reduced the price of rice to less than 50% in real terms over the past three decades. Continuing increase in population coupled with decreasing arable land, water and other resources for sustaining agriculture make it especially important to maximize rice production. Tapping into the genetic potential of rice gene pool is the most feasible strategy for developing rice varieties for increased productivity. The availability of diverse genetic resources and knowledge is fundamental to any successful pant improvement program. Yet, this is also the most contentious issue confronting public research institutes at a time when private sector is increasing investment in crop research that has been done largely by public sector. This issue is particularly sensitive with rice.

On the one hand, the private investment can bring about innovations. On the other hand, a shift in the balance of public and private investment in rice research has also raised concerns that some proprietary technologies might become unavailable to those who cannot afford them. Such concerns must be considered because gene identification, validation and application are occurring at an ever-accelerating pace. The question is, can the model of free access to genes; germplasm and knowledge exist and contribute under an increasingly protective environment that exercises intellectual property rights.

The public rice genome-sequencing project (IRGSP) was initiated in 1998 under the leadership of Japan Rice Genome Research Program (RGRP). Eight other countries: China, Taiwan (China), India, Korea, Thailand, France, USA, and Brazil have participated in the project. The completion of the sequencing project was announced in December 2004. Two private companies, Syngenta and Monsanto, as well as public Beijing Genomics Institute (BGI) contributed their genome sequence data that facilitated and expedited the completion of the project.

The completely sequenced and freely accessible rice genome promises an enormous pool of genes and genetic markers for improvement of rice and other cereals through marker aided selection and genetic transformation. However, to exploit this information will require detailed genetic and phenotypic analysis to identify and understand function of each of more than 60,000 rice gene sequences. Both public and private resources are needed to exploit the potential offered by genomics. Diverse resources held by rice growing countries and IRRI are crucial for success, and these include mutants, germplasm, near-isogenic lines, population for gene mapping and elite breeding lines for diverse rice growing conditions. The private sector has greater capacity in molecular skills, tool ownership and most importantly, access to capital markets to undertake detailed molecular analysis that employs new sequencing and bioinformatics tools and large databases.

In order to enhance public-private collaboration, IRRI proposed formation of an International Working Group on Rice Functional Genomics in 1999. It was agreed that the following activities are of high priority: (1) create an information node to deposit and disseminate information on rice functional genomics, (2) build a public platform to promote access to genetic stocks and phenotypic information, (3) develop databases on phenotypes and mutants with linkage to sequencing laboratories, and (4) initiate partnership to develop resources for microarray analysis.

The pattern of rights envisioned is that genetic resources for functional genomics will be made available to the public and private sectors under a material transfer agreement (MTA). This agreement permits recipients to obtain patents on genes discovered with material, but requires them to make available rights under those patents at a reasonable royalty for application in commercial markets of developing world and at zero royalty for application in noncommercial subsistence farming. In addition to ensuring the possibility of use in the developing world, it is essential that data and materials are freely available for research. Hence, the MTA has provisions permitting free use for research purposes of any of the patents, as well as provisions ensuring that recipients cannot obtain any form of intellectual property on the genetic stocks per se. The information gained from research with such genetic resources must be provided back to the public; albeit after an appropriate delay to allow patenting. Public institutions engaged in developing and studying these genetic resources must agree among themselves to supply materials and to exchange all information developed and maintained in a common database. They must also follow the same rules as those imposed on the private sector through MTA.

The experience of last four years shows that this is a workable model. The International Working Group on Rice Functional Genomics was converted into International Consortium on Rice Functional Genomic (IRFGC) on the basis of discussions among participants at International Conference on the Status of Plant and Animal Genomic Research II in San Diego in January 2003.

Conclusions

As the foregoing discussion shows both the public and private, organizations have important roles to play in harnessing the benefits of biotechnology and emerging field of genomics. Collaboration between the two sectors is even more crucial for addressing the problems of food security and poverty alleviation in developing countries. As the examples of public-private collaboration cited in this paper show, large life science companies such as Monsanto. Syngenta, Pioneer are willing to donate their proprietary technologies (genes, promoter, process and sequences) for humanitarian causes. Choosing which materials and tools to use in the lab is an important juncture where increased knowledge about IP can help avoid later proprietary claims to innovation. Public intellectual property resource for agriculture (PIPRA) (www.pipra.org) based at the University of California has a database related to patents and patent application owned by members and can be easily accessed through an on-line interface.

In addition, the formation of global public-private alliances and international agreements will be critical to ensure that the current explosion in genomics knowledge can be tapped to solve the problems of poor producers and consumers. The public sector has critical assets in the form of germplasm and associated biological knowledge important in new science of genomics. However, to fully exploit these assets, public sector must develop a capacity in IP management, strengthen biosafety protocols and upgrade business skills. Most public-private alliances to-date have been based on free access to proprietary technologies for non-competing markets. Market segmentation is likely to be a key element in public-private negotiations in the future. To ensure that public sector organizations in poor developing countries have access to proprietary technologies, multinational life science companies should have enlightened patent policy like that of Danforth Plant Science Center, Saint Louis, USA. It states; "Any licensing agreements from discoveries made at the center shall diligently and in good faith negotiate the terms of the exclusive worldwide license, making provision for preserving the availability of the intellectual property for meeting the needs of developing countries"

Trust for Advancement of Agricultural Sciences (TAAS)

GOAL

An accelerated movement for harnessing agricultural sciences for the welfare of the people.

MISSION

To promote growth and advancement of agriculture through scientific interactions and partnerships.

OBJECTIVES

- Sponsoring seminars and special lectures on emerging issues and new developments in agricultural sciences in different regions of India.
- Promoting local lecture tours and visits to institutions within country of the eminent scientists from international organizations abroad and of the academicians of foreign agricultural academies visiting India.
- Facilitating partnership with non-resident Indian agricultural scientists visiting India on sabbatical or short leave.
- Instituting awards for outstanding contributions to Indian agriculture by scientists of Indian origin abroad.
- Arranging special lectures of eminent agricultural scientists in various schools in different parts of the country.
- Providing support to agricultural scientists for participation in conferences/ seminars, in India and abroad, for oral presentation of their research work.
- To act as think tank on key policy issues relating to agricultural research for development (ARD).