T O D A Y

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Abstract ¹

Accessing Modern Science:

Policy and Institutional Options for Agricultural Biotechnology in Developing Countries ²

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While the private sector dominates biotechnology research, there are significant market failures in harnessing this research for the benefit of poor producers and consumers in developing countries. The public sector, national and international, will have to play a major role in filling this gap, and to do so will have to build capacity to develop innovative partnerships with the private sector in order to gain access to needed research tools and technologies. The paper highlights the complexity of the challenge in developing new forms of collaboration between a variety of actors in the biotechnology area in developing countries: national research systems with very diverse capacities in biotechnology, international research centers, local private R&D companies, global life science companies, and advanced research institutes in both industrialized and developing countries. Examples and case studies are provided from strong programs (such as India, China, and Brazil), which will be tool developers as well as users. Other programs are developing an adaptive capacity in biotechnology to use tools and methods developed elsewhere, but a large number of countries currently have research systems with virtually no capacity in molecular biology. Each type of program presents special challenges and opportunities for accessing the new technologies, based on facilitation of private investments, public-private partnerships, local capacity to design around proprietary technologies, working with CGIAR centers as intermediaries and partners, and regional collaboration and consortia. Policy and institutional issues for accessing modern science are then discussed at various levels-research institute, national, regional, and global. Many of the challenges involve developing appropriate strategies and capacities in the management of intellectual property within the public sector. Public research organizations will also need to define their bargaining chips and assert ownership, while developing innovative means of segmenting markets that complement private sector interests.

¹ Byerlee, D. and K. Fischer. 2001. Accessing Modern Science: Policy and Institutional Options for Agricultural Biotechnology in Developing Countries. *IP Strategy Today* No. 1-2001.

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1. Introduction

Modern biotechnology based on molecular biology is generating revolutionary advances in genetic knowledge and the capacity to change the genetic makeup of crops and livestock. The rapidly expanding field of genomics is providing new molecular tools to greatly accelerate and more precisely target conventional breeding. This same knowledge is being applied to transfer genes across (and within) species to create transgenic varieties (popularly known as genetically modified organisms). These new approaches require advanced skills, research laboratories, the capacity to manage intellectual property (IP), and in the case of transgenics, the capacity to evaluate environmental and health risks.

In the past year, a number of influential organizations and individuals have strongly endorsed the significant *potential* of modern biotechnology in developing countries to raise agricultural productivity in a more environmentally-friendly manner, enhance food security, and contribute to the alleviation of poverty (Royal Society of London, 2000; Nuffield Council on Bioethics, 1999; Conway, 1999; Pinstrup-Andersen & Cohen, 2000; Persley & Lantin, 2000; Serageldin & Persley, 2000; Spillane, 2000). This potential is particularly relevant given the enormous challenge of increasing food security in the developing world and the growing evidence that gains from conventional sources of technology are slowing.

To date, the application of molecular biotechnology has been limited to a small number of traits of interest to commercial farmers, mainly developed by a few 'life science' companies operating at a global level. Very few applications with direct benefits to poor consumers or to resource-poor farmers in developing countries have been introduced. Although much of the science and many tools and intermediate products can solve high priority problems in the tropics and subtropics, it is generally agreed that the private sector will not invest sufficiently to make the needed adaptations. Consequently, national and international public sectors in the developing world will have to play a key role, much of it by accessing proprietary tools and products from the private sector. However, there has been little detailed analysis of the incentives and mechanisms by which such public-private partnerships can be realized.

The aim of this paper is to provide a broad framework for assessing a range of policy and institutional options available to developing countries for generating and accessing these new molecular tools at the national, regional and global levels, with particular emphasis on crops. After a synoptic overview of the status of biotechnology research in and for developing countries, various mechanisms for accessing modern tools and technologies are outlined and analyzed for their potential cost effectiveness, using available examples. The main section of the paper discusses institutional and policy options for facilitating this transfer within a framework of public and private bargaining chips and segmented markets. Special attention is given to how strategies can be adjusted to fit the very different capacities among developing countries in biotechnology research.

2. Current Status of Biotechnology Research in Developing Countries

Biotechnology research is currently being carried out in both public and private organizations, which may have either national or multinational mandates. These initiatives can be broadly divided into:

- i. largely global private sector firms,
- ii. public sector research organizations in national agricultural research systems (NARSs), including universities,
- iii. public research organizations in industrialized countries, including universities,
- iv. the international agricultural research centers (IARCs) of the Consultative Group on International Agricultural Research (CGIAR), and
- v. various other international initiatives funded by donors of industrialized countries, multilateral development banks, and nonprofit foundations.

2.1 The private sector

There is little doubt that the private sector is the major player in biotechnology research globally. The major life science companies invested some US\$2.6 billion in agricultural research and development (R&D) in 1998 (www2.aventis.com/introduce/rddia_2.htm), with perhaps 40% of this allocated to plant biotechnology. This is consistent with a 1996 estimate of total private investment in agricultural biotechnology, including smaller biotechnology companies, of US\$1.5 billion (CGIAR, 1997).³

A small share of this private R&D is directed at developing countries. Much of it is occurring through direct investment by the global life science companies, acquisition by these companies of seed companies in developing countries, and through alliances between global and local companies. Table 1 shows that with few exceptions, each of the major life science companies has a significant presence in the developing world, although this is highly concentrated in a few large countries.

| Parent Company | India | China | S.E.Asia | South Africa | Brazil | Argentina |
|--|--|--|---|--|--|-------------------------------|
| Monsanto/ Pharmacia (Holdens, DeKalb, Asgrow, Cargill International, Delta & Pineland*) | MAHYCO (joint vent. for cotton; 26% share of MAHYCO stock) E.I.D.Parry (maize, sor- ghum and sun- flower with DeKalb), Cargill | CASIG (maize with DeKalb) Xinjiang and Shaanxi Pro- vincial Seed- Cos Hebei Provin- cial Seed Co.(cotton) Cargill (Liaon- ing) | DeKalb (joint vent. with Charoen Pakphand) Cargill | Delta & Pine- land* Calgene Carnia (Car- gill) | Agroceres Asgrow BrasKalb Monsoy Cargill | Asgrow, DeKalb, Cargill |
| Du Pont (Pioneer Hi-Bred Int.) | Joint Venture with Southern Petrochemicals | Pioneer Re- search Sub- sidiary | Pioneer | Pioneer | Pioneer | Pioneer |
| Aventis (AgrEvo, PGS, Nunhems, Sunseeds) | Proagro first joint with PGS, then in 1998 Agrevo pur- chases Proagro. Sunseeds | Sunseeds joint vent. | Sunseeds | Aventis | Aventis Granja 4 Irmaos S.A. (rice) | Aventis |
| Syngenta (Merger of Novartis and Astra/Zeneca. Northrup King, Rogers, S&G Seeds, Hilleshög through Novartis; rights to tech- nology but not to germ- plasm of Advanta from Zeneca) | Novartis (was Sandoz) ITC/Zeneca | | Novartis | | Northrup King | Northrup King |
| Dow (Mycogen, Cargill USA and Canada) | | | | | Dinamilho Hibridos Colorado | Morgan SA |
| Empresas La Moderna (Seminis, Peto, Asgrow- vegetables) | Seminis | Petoseeds has joint vent. with CASIG and subsdiary in Shanghai | Petoseeds | | Petoseeds | |
| Strategic alliance, n | ot ownership. | | | | | |

Table 1: Overview of Mergers and Acquisitions (in parentheses) in Developing Country Seed Industries Related to Global Life Science Companies

Source: Updated slightly from Pray (pers. comm.) but subject to continuous change.

³ This is undoubtedly an underestimate because of the considerable spillovers from the much larger investment in pharmaceutical and medical biotechnology research to agricultural biotechnology research,

A second group of private firms is the smaller biotechnology companies that specialize in biotechnology research. While most of these are located in the industrialized world, and many work through partnerships with the global life science companies, they own tools and products and have specialized skills that are often relevant to developing world problems. However, this group has little direct investment in developing countries, except for a small number of companies located in a few large developing countries.

Finally, there are also important local seed companies that carry out R&D in developing countries, although many have been acquired in recent years by the global companies.⁴ Only a few local companies have a capacity in biotechnology research, and in nearly all cases, their research is carried out as part of an alliance with one of the global companies.⁵

The private sector has focused its investments on commercial agriculture in the industrialized countries and a few developing countries. However, the private sector has also invested in R&D for crops, such as rice, which are largely grown by resource-poor farmers in developing countries. Already the private sector is a major player in developing countries for R&D on hybrid crops, such as maize (Morris & Ekasingh, 2000), and its role in other major food crops will expand. Private R&D has emphasized commercial areas such as the southern cone of Latin America, but even in markets with relatively small farmers, such as Central America and the Andean Region, private R&D for crops, such as maize, now exceeds that of the public sector (Table 2).

For non-hybrid crops, private companies are mostly conducting research in areas with large seed markets and where intellectual property rights (IPRs) laws are in effect and can be enforced (Teng, Stanton & Roth, 2000).

| | No. of Countries | Maize area (million ha) | Public research (US\$ million) | Private research (US\$ million) | Total research (US\$ million) |
|--------------------------------------|---------------------|-----------------------------------|-----------------------------------|------------------------------------|----------------------------------|
| Central America and Caribean | 9 | 2.1 | 0.6 | 0.5 | 1.1 |
| Andean zone | 6 | 2.3 | 1.5 | 2.3 | 3.8 |
| Sub-Total | 15 | 4.4 | 2.1 | 2.8 | 4.9 |
| México | 1 | 7.6 | 3.7 | 4.1 | 7.7 |
| Southern Cone | 2 | 16.4 | 5.1 | 23.7 | 28.8 |
| Subtotal | 3 | 24.0 | 8.8 | 27.8 | 36.5 |
| Total | 18 | 28.8 | 10.9 | 30.6 | 41.4 |
| Source: Morris & López-Pereira, 1999 | | | | | |

Table 2: Investment in Maize Breeding Research in Latin America, mid 1990s

2.2 Public sector NARSs in developing countries

The public sector finances around 90% of total agricultural research in developing countries, compared to about half in industrialized countries (Pray & Deininger-Umali, 1998). There is a huge diversity among national agricultural research systems (NARSs) in developing countries with respect to their capacity in agricultural biotechnology R&D. Table 3 presents a highly simplified view of differences in their plant breeding and biotechnology research capacity, divided into three broad groups:

⁴ For example, Monsanto has reportedly purchased 16 local seed companies in Brazil.

⁵ For a good example of alliances between a multinational and a local company in India, see Mabashir (1999). Most large Indian seed companies have formed alliances with global life science companies.

- 1. A few Type I NARSs (India, China, Mexico, Brazil, and South Africa) have strong capacity in molecular biology, including 'upstream' capacity often located in universities, to develop new tools for their own specific needs.
- 2. Type II NARSs (e.g., Thailand, Philippines, Pakistan, Colombia, Uruguay, and Kenya) have considerable capacity in applied plant breeding research, as well as capacity to 'borrow' and apply molecular tools (e.g., markers and transformation protocols) developed elsewhere.
- 3. A large group of Type III NARSs (many in Africa) has very fragile capacities in plant breeding and virtually no capacity in molecular biology.⁶ These countries largely depend on the introduction and testing of varieties from abroad, especially from the CGIAR system.

Most Type I and II NARSs have also instituted a regulatory framework for the testing of transgenic crops and for the protection of IP, although capacity to evaluate risks and to manage IP is often weak. Most Type III NARSs do not have a regulatory framework in place even to import and test transgenic products.

| | Type 1 NARSs: | Type II NARS: | Type III NARSs: |
|----------------------|--|---|---|
| Markata sina in | very strong | Medium to strong | Fragile or weak |
| Markets size in | Large to very large | Medium to large | Small to medium |
| terms of poten- | | | |
| | | NI 11 11 | |
| Plant breeding | Strong national commodity pro- grams with comprehensive breeding programs, including some pre-breeding. | National commodity pro- grams that are generally strong in applied breeding | Usually small and fragile programs with success de- pendent on one or two indi- viduals. Usually conduct own crosses although value added of local adaptation often low due to small mar- ket size |
| Use of IARC | Used as parents to obtain specific | Very important as parents, | Mostly direct releases after |
| materials in | traits for breeding and pre- | and also as direct releases | local screening and testing |
| breeding | breeding, and sometimes re- | | |
| | leased directly. Also use early | | |
| Piotochnology | Capacity in molecular biology as | Heusly developing capacity | Vonulittle or ne capacity in |
| research | arost or grostor than most | in molecular biology but | molocular biology although |
| research | IABCs Marker assisted selection | with considerable support | many have capacity in tis- |
| | hoing incorporated into brooding | from donors and IAPCs | |
| | programs Considerable research | Potential to participate as | sue culture. |
| | on transgenics. Growing capacity | nartners in genomics in | |
| | in genomics and participants in | screening germnlasm | |
| | international genomics networks. | screening gernipidsin | |
| Basic and | Often considerable capacity to | May have capacity in spe- | No capacity |
| strategic re- | develop new tools and products | cific areas | |
| search in plant | that can match that in many in- | | |
| breeding and | dustrialized countries | | |
| biotechnology | | | |
| Private sector | Private sector very active for | Private sector activity in- | Little private sector activity |
| | hybrid crops and increasingly for non-hybrid commercial crops | creasing and usually in- volved in hybrid crops | for food crops |
| Regulatory | Framework in place although | Most countries have, or | Most countries do not have |
| framework for | capacity to implement is modest | soon will have framework, | regulatory framework |
| biosafety and IPR | and untried. | but weak capacity to im- | - |

Table 3: Summary of Plant Breeding and Biotechnology Capacities of Different NARSs Types

⁶ These countries are the largest in terms of the number of countries, corresponding to Falcon's (2000) 70 poorest countries in terms of incomes and research capacity. However, in terms of total population and absolute number of poor, Type I and II NARS dominate.

On average, NARSs invest 5-10% of their total research expenditures in agri-biotechnology (Janssen, Falconi, & Komen, 2000), concentrated in Type I and a few Type II NARSs. In four countries where detailed data are available (Kenya, Mexico, Indonesia, and Zimbabwe), public-sector organizations, including universities, accounted for 92% of research expenditures on agricultural biotechnology during 1985-1997 (Janssen, Falconi, & Komen, 2000). Donors accounted for a considerable share of this investment—around 60% in the case of Kenya and Zimbabwe. No estimates are available on overall investments by NARSs in biotechnology, but given available data, a rough guess is that they are investing at least US\$ 150 million annually from their own resources (i.e., excluding donors), which is several times the investment of the CGIAR.

2.3 Public research organizations and universities in industrialized countries

Public organizations and universities in the industrialized countries carry out a considerable amount of biotechnology research, with a small amount oriented toward developing-country agricultural problems (usually funded by donors). Total public investment in crop biotechnology research in these countries may approach US\$1.0 billion.⁷ This is a large sum, and many of the tools and products of this research are potentially useful to developing countries. However, developing-country access to these tools and products is restricted both by the strong trend of these organizations to protect and market their IP and by the increasing number of alliances between these organizations and the private sector. Indeed, the traditional distinction between public and private sectors has become blurred.

2.4 The CGIAR

Collectively, the CGIAR Centers invest around US\$ 25 million annually in biotechnology, representing 7.7% of the total CGIAR budget. With a relatively small investment, the Centers have made substantial progress in developing molecular methods to analyze genetic diversity, marker-aided selection in breeding, and transgenics (Morris & Hoisington, 2000; Technical Advisory Committee, 2000). Some centers are also developing capacity to participate in functional genomics research.

The emphasis of the centers is on applied research aimed at selected traits and crops that complement private-sector efforts. Once their own capacity has been established, centers are turning to capacity building and networking in client countries. However, IARCs have invested little in strengthening capacity in policy and regulatory issues related to the deployment of biotechnology products⁸, and they have shied away from actively participating in public dialogue surrounding transgenics (Morris & Hoisington, 2000).

2.5 Donor support and multinational initiatives

Donor contributions to biotechnology research in and for developing countries have been summarized in Horstkotte-Wesseler & Byerlee (2000). They estimate that donors provide between US\$ 40 million and US\$ 50 million per year for agri-biotechnology, not including the US\$ 25 million spent by the CGIAR on biotechnology. However, this investment is concentrated in just a few countries, nearly all with Type I and II NARSs. The focus of this support varies substantially from directly funding research (e.g., the

⁷ Given a research intensity of 2.4% (Alston, Pardey & Roseboom, 1998), total public investment in agricultural R&D in industrialized countries in 1999 was about US\$11 billion. The US public sector invested some 16% of its budget in biotechnology research in 1997 (Heisey, pers. com.). If the share to biotechnology in the US is applied to all high-income countries, total public spending on biotechnology research would be about US\$1.8 billion, and again using the US proportion, about half of this would be for crop biotechnology.

⁸ ISNAR has a special International Biotechnology Service for capacity building through training and technical advice, discussed below.

Rockefeller Foundation), supporting public-private partnerships and technology transfer (e.g., USAID), capacity building (the World Bank), and participatory needs assessment (the Netherlands).

There are also a number of multi-donor global initiatives, including:

- **IBS**, the Intermediary Biotechnology Service at ISNAR, which acts as an independent advisor to developing countries on matters of biotechnology policy and management
- **ISAAA**, the International Service for the Acquisition of Agri-biotech Applications, hosted by Cornell University, with regional centers in Africa and Asia, which specializes in the transfer of technology from the private sector to developing countries, including capacity development in biosafety and IPR.
- **CAMBIA**, the Center for the Application of Molecular Biology to International Agriculture, an independent, nonprofit research institute located in Australia that conducts research and provides training and technology transfer services for developing countries (including advice and data bases on IPR matters).
- **ICGEB**, the International Center for Genetic Engineering and Biotechnology, established as an intergovernmental initiative within the UN system, which is mostly engaged in more basic research as well as training.

While the amount of donor funding for biotechnology is relatively small, these funds constitute a considerable proportion of total public investment in agricultural biotechnology R&D in developing countries, especially outside of the three "NARS giants"—India, China and Brazil. However, the effectiveness of donor support has been limited by:

- i. a focus on first generation products based on the supply of technology rather than on demands reflecting the priorities of poor producers and consumers (Cohen, 1999),
- ii. fragmentation and 'projectization' of donor efforts with no clear international consensus on priorities to guide a coordinated multi-lateral effort on traits for the poor,
- iii. overemphasis on technology development at the expense of investment in national regulatory systems and public dialogue to facilitate in-country testing and risk evaluation, and
- iv. a focus on public sector investments with little attention to utilizing the large capacity in the private sector, or to accessing currently available tools and technologies from the private sector to be employed for achieving wider social benefits (USAID and ISAAA are notable exceptions) (Horstkotte-Wesseler & Byerlee, 2000).

3. Mechanisms for Accessing Technology in an Era of Privatization

A central issue for both public and private sectors is that many of the biotechnology tools and products of potential value to resource-poor farmers and consumers have complex patterns of ownership in an increasing web of cross licensing and mergers. The case of enhanced Vitamin-A rice, which is reported to be based on technologies protected by up to 70 patents originally held by 31 different organizations, highlights the complexity of ownership pedigrees (Kryder, Kowalski & Krattiger, 2000).⁹ Each owner of the component technologies will have different expectations for the use of his/her technology in different organizations and in different markets. The process is further complicated by the fact that individual component technologies may be protected in some countries but not in others.

Essentially there are four broad options for public policy:

⁹ Most of these patents are held by private firms, but six universities (4 public and 2 private) are also owners of components. Note that the IP complexity of the enhanced Vitamin-A rice is probably higher than most current products on the market since several genes are involved. However, the IP complexity of vitamin-A rice may be more representative of the next generation of products.

- i. leave technology transfer entirely in the hands of the private sector,
- ii. develop a public program independently of the private sector (i.e., designing around proprietary products),
- iii. negotiate public sector access to relevant proprietary technologies through a range of commercial and non-commercial arrangements, and
- iv. negotiate public-private alliances and joint ventures to develop appropriate technologies.

As we show below, the relevance of each option is very case specific, depending on the type of NARS, the crop, and the trait of interest.

3.1 Leaving it to the private sector

The first option that should be considered in accessing the relevant knowledge and technologies is to promote technology transfer through the private sector. It is commonly stated that the private sector will only invest for commercial markets characterized by medium- and large-scale farmers or commercial crops. However, there are several reasons to expect that the future role of the private sector in developing countries may be underestimated. First, the marginal cost of moving some tools and technologies originally developed for commercial markets into emerging markets may be low. Second, the policy environment for the private sector in developing countries is being liberalized, leading to rapidly increasing private sector activity in seed markets. Third, biotechnology itself will facilitate protection of IP in the medium term, especially in markets for small-scale farmers where it is not cost effective to enforce IPR laws at the farm level. The private sector is developing trait-specific technology protection systems—biological/chemical approaches to IP protection that allow trait expression only through the application of a proprietary chemical—and applying biotechnology to increase the efficiency of hybrid seed production in self-pollinated crops such as rice and wheat. In some cases too, especially with output traits such as quality, the private sector may be able to develop specific contractual production and sales relationships with small-scale farmers.

But outside of specific crops and regions, the role of the private sector will be limited for the foreseeable future. Private firms under-invest in agricultural R&D due to well-known market failures such as spill-overs and the difficulties of appropriating research benefits. Due to a number of special characteristics of biotechnology research, market failures are endemic for biotechnology (Rausser, 1999), especially for resource-poor farmers in developing countries. These include the high fixed cost of much of the research, the need to operate in large markets to recuperate fixed costs, and poorly developed seed markets in developing countries. Several market failures also occur in accessing and protecting IP, including weak IPR laws for biological inventions in most countries, high cost of enforcement of IPRs in small-scale agriculture, the complexity and fragmentation of IPRs leading to high transactions costs to negotiate licenses, and ill-defined rights on the scope of biotechnology inventions. Finally for transgenic products, high *initial* costs of the development phase are likely because of the cost of passing early technologies through biosafety and food safety regulations (because of inexperience and, in some cases, negative public perceptions) and because of the considerable informational efforts required for farmers to adopt these technologies (Tripp, 2000).

These various types of market failures mean that the public sector will have to play an important role in serving resource-poor farmers, at least in the initial stages. However, the private sector can be expected to play a lead role for commercial crops, such as cotton, hybrid crops (maize and some oil-seeds), and single-trait transgenics for pest resistance and herbicide tolerance in favored areas, even for small-scale farmers. An important policy issue is to ensure that the public sector complements private R&D. Public research is often critical to reducing the cost of entry for private firms (Pray & Deininger-Umali, 1998). For example, the public sector has facilitated the entry of the private sector into hybrids by developing the first generation of inbreds. Once a competitive private-sector market is oper-

ating, the public sector can redirect those resources toward farmers and environments that are not being targeted by the private sector and backstop private-sector research with longer-term research on complex traits with more uncertain outcomes.

For agricultural research in general, and for biotechnology in particular, most public sector organizations have yet to formulate a strategy to complement private sector research. For example, Hossain et al. (2000) analyzed the content of rice biotechnology programs in Asian public NARSs and found that a large proportion of the projects address many of the likely targets of the private sector, especially insect and disease resistance and herbicide tolerance in favorable ecosystems. Similar duplication was found in a recent World Bank review of biotechnology research in the Indian public sector. However, the public sector is gradually increasing attention to abiotic stresses and yield and nutrition traits that appear to receive less attention by the private sector.

3.2 Relying only on the public sector

Another option is for the public sector to develop a program independently of the private sector by 'designing around' protected tools and products through its own inventions that do not infringe on the IP of others. This might be possible and even efficient if the cost of the research is less than the cost of accessing equivalent technologies from elsewhere. It is most likely to be applicable to fill gaps in a tool kit acquired by a variety of means and where FTO is needed to develop and release finished products (e.g., varieties). Since a considerable number of tools are needed for even relatively simple genetic transformations, developing a complete tool kit free of IP encumbrances is not likely to be efficient in terms of resource use and time. Nonetheless, public research organizations in China and India appear to be have developed their own transformation protocols for Bt cotton (Pray et al., 2000), although it is likely that they have used, legally or otherwise, some proprietary tools as well.

A closely related possibility is to redesign the components of a product to reduce the number of patents on a desired product. The recent review of the IP profile of enhanced Vitamin-A rice by Kryder, Kowalski & Krattiger (2000) found considerable potential to carry out further research on redesigning components to reduce the cost and complexity of IP negotiation. The costs of the additional research, however, need to be balanced against the costs of IP negotiations.

Finally, there are some public domain technologies available in industrialized countries that are freely available, many of which are potentially useful for developing countries (Spillane, 2000). The number of such technologies may increase as patents expire for first generation technologies.

These various options for designing around proprietary tools and products should definitely be explored by very strong Type I NARSs. However, the bottom line is that "in an increasingly globalized world, no country can make technological progress in isolation, and cross-country collaborations can most readily be based on a common set of IPR principles." (Barton, Lesser & Watal, 1999; p. 8).

3.3 Accessing proprietary technologies

The third major option is for the public sector to access proprietary tools and technologies, usually from the private sector but sometimes from other public organizations. Opportunities for the public sector to access proprietary tools and technologies will differ widely depending on the technology, its use in commercial or noncommercial markets, and the business interests of the owners. Several business and legal options have been used by the public sector to gain access to proprietary technology (Erbisch & Fischer, 1998), such as confidential agreements, material transfer agreements, licensing, purchase, and joint ventures. To date there is little experience in developing countries with these various types of agreements, and it is still too soon to delineate general patterns of technology transfer arrangements that can be used as models for others.

3.3.1 Unilaterally accessing technologies

One option is for the public sector 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 often perfectly legal if patents for the technology have not been lodged in the country where the technology will be used and if the product is not exported to a country where there is protection on the invention. This is most likely to occur in countries with Type III NARS. In reality, however, many critical and enabling technologies for biotechnology have been widely patented in many countries, especially with Type I and II NARS, making it essential to gain freedom to operate (FTO) before releasing a new product.

A recent review of the patent pedigree of enhanced Vitamin-A rice (Kryder, Kowalski & Krattiger, 2000) provides good insights into the pattern of patent protection (Table 4). While they identified 44 potential patents related to this rice in the USA, the number of relevant patents in different developing countries varies from zero to 11. All Type I NARSs would face patent restrictions, but there is no clear relationship between the number of potential patents, the importance of rice, and the strength of the public sector research program. No patents have been taken out or filed in Thailand (a country with intermediate ca pacity in biotechnology), while patents have been taken out or filed for several of the components in countries with little capacity in molecular biotechnology (e.g., in some African countries). However, even Thailand and other countries (Pakistan and Uruguay) with no relevant patents would face difficulties in employing the option of unilateral access since they are major rice exporters to countries where patents are held. Exports in such cases would require that countries develop efficient systems to segregate production.

But even when strictly legal, unilateral access is unlikely to be a viable strategy for most public NARSs for a number of reasons:

- i. the complexity of many tools does not allow for easy copying,
- ii. the necessity of obtaining associated "know how" and training to effectively use the tools,
- iii. the rapid advances in science that will likely leave the public sector working with outdated tools,
- iv. the fact that several partners are often involved in the transfer of a tool or technology and the reputation and IP status of all partners must be considered, and
- v. the limitations on international trade in derived products imposed by unauthorized access.

Nonetheless, for many Type III NARSs serving smaller markets, and for orphan crops, unilaterally importing transgenic varieties or crossing with local materials without considering IP may be the most cost-effective approach to accessing the technology since it avoids establishing expensive laboratory and IP management capacity.

3.3.2 Purchasing outright

Another approach is for the public sector to buy ownership of key proprietary technologies for use in developing countries. For example, a consortium of public-sector institutions in Asia, led by IRRI, purchased the rights to a *Bt* gene owned by a private Japanese company. The consortium then decides whether to make these materials public property or allow others to use the gene, subject to royalty payments. Likewise Cohen et al., (1999) report over 50 instances where Latin American NARSs have purchased proprietary biotechnology tools and products.

A variant of this approach would be to contract with the private sector (or a public supplier), perhaps through competitive bidding, to *develop* a specific tool, but with the public sector retaining ownership of the product. This is most appropriate where the "know how" exists in the private sector to adapt a product to a specific situation with considerable certainty. It also requires international funding (such as a global fund discussed below) since few NARSs have sufficient resources to interest the private sector.

| Country | Rice Production (Mt), 1998 | % Exported 1998 | Number of Patents |
|---|----------------------------|-----------------|-------------------|
| China | 200.6 | 1.9 | 19 |
| India | 127.5 | 3.8 | 5 |
| Indonesia | 49.2 | 4.0 | 6 |
| Bangladesh | 28.3 | 0 | 0 |
| Vietnam | 29.1 | 13.1 | 9 |
| Thailand | 22.8 | 27.9 | 0 |
| Myanmar | 16.7 | 0.6 | 0 |
| Japan | 11.2 | 0 | 21 |
| Philippines | 10.2 | 0 | 1 |
| USA | 8.5 | 36.5 | 44 |
| Brazil | 7.7 | 0 | 10 |
| Pakistan | 7.0 | 26.6 | 0 |
| Egypt | 4.5 | 9.6 | 0 |
| Nepal | 3.6 | 0 | 0 |
| Nigeria | 3.3 | 0 | 0 |
| Cote d'Ivoire | 1.4 | 0 | 10 |
| Uruguay | 0.9 | 75.4 | 0 |
| Senegal | 0.1 | 0 | 0 |
| Source: Kryder, Kowalski & Krattiger (2000) and FAO statistics (www.fao.org). | | | |

 Table 4:
 Number of Patents on Vitamin-A Rice, Level of Rice Production, and Percent Exported, by Country

3.3.3 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 decisions" (Rausser, 2000) about priorities and resource contributions. Up-front costs are minimal and risks are reduced because the negotiation of the use value occurs after the value of the product, if any, is known. However, this practice can also weaken the negotiating position for licensing for the use phase, since the greater the success of the research, the greater the value of the technology and therefore the greater the expectation of returns 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 on the "back-end decisions" on commercialization and royalty sharing.

Where products are to be commercially used, licensing is the most widely used method to transfer technology and associated know how. The license contractual agreement specifies the terms of use of the products and the sharing of benefits from their commercial application. Cross licensing is also often used to allow parties to exchange technologies. Licensing requires considerable skills in IP, negotiation, and business planning, and often entails high transaction costs due to the complexity of "IP pedigrees" (i.e., the tracing of the IP of all component technologies and processes used to produce a commercial product, also known as product clearance profiles).

3.4 Alliances and joint ventures

Alliances and joint-venture agreements usually involve licenses and MTAs for sharing and accessing technologies. In joint ventures, each party, public and private, contributes specific assets or knowledge and shares benefits according to an *a priori* agreement. Joint ventures between the public and private sectors are becoming more common in accessing biotechnology tools in developing countries. As Rausser (1999; p. 6) (quoting Mowery) notes, "it is generally impossible to internalize all R&D that is

needed to integrate the technical know how to arrive at market place products. Accordingly the demand for alliances, joint ventures, and institutional arrangements has never been greater".

The number of different types of potential alliances for biotechnology research is enormous. Simply considering only two-way alliances among major categories of actors, public and private, and national and international, and adding advanced public research institutes and smaller biotechnology companies (mostly located in industrialized countries) creates numerous possibilities, and all combinations are possible—in fact most are found in practice (Figure 1). The potential for three- or even four-way alliances among categories complicates the issue even more. Thus the number of options open to public-sector NARSs for accessing technology through alliances is very large.

The Agricultural Biotechnology Support Program (ABSP), financed in part by USAID, provides several useful case studies of joint ventures for public-private collaborative research in biotechnology (Lewis, 2000). One of the most successful of these projects is a joint venture between Pioneer Hy-Bred International Inc., a large private multinational company (now acquired by Dupont), and the Applied Genetic Engineering Research Institute (AGERI), an Egyptian public research institute, to jointly develop *Bt* maize. In the collaboration, the Egyptian public system gains access to expertise to develop the local strain of *Bt* (the innovation) and to train its staff. In turn, the private company has access to the new *Bt* strain for use in markets outside of Egypt. A different type of joint venture widely used in the industrialized world has been signed between Monsanto and the Indian Institute of Science, allowing the public sector to carry out more basic research upstream in the technology chain. CGIAR centers are also developing a number of joint ventures and agreements with private companies (e.g., CIMMYT, 2000). Appendix 1 provides a novel proposal for such partnerships in the emerging field of genomics.

Although conceptually simple, alliances and joint ventures between the public and private sector often require considerable nurturing due to differences in business cultures and the lack of experience with IP management in public organizations. An intermediary institution has often been useful in facilitating an agreement (e.g., Michigan State University in the case of ABSP), as is the seed funding provided by that institution.





ARI: Advanced Research Institute.

4. Public-Private Partnerships, Complementary Assets & Market Segmentation

It is clear from the above discussion that the public sector will have to play a key role in biotechnology R&D in developing countries but that working alone the public sector will make slow progress. Thus public-private partnerships will be a central element of any R&D strategy. Negotiating successful public-private partnerships revolves around defining goals, identifying complementary assets, and analyzing the potential to segment markets for different partners (Rausser, 2000; Van der Meer, 2000). Public and private partners also need to recognize important differences in their values and culture. Considerable time and patience is needed to bridge these cultural divides and establish mutual trust and confidence. With experience, however, the cost of negotiating such partnerships should fall (van der Meer, 2000).

The stated goal of most public research organizations is to maximize societal benefits, usually defined in terms of economic benefits, including benefits to the poor, although the reality may be different due to internal incentive structures and external political pressures. Private firms operate to maximize profits within acceptable levels of risks in order to give good returns to their shareholders and protect their competitive edge. Both partners incur research costs, as well as costs of accessing and protecting IP and enforcing IPRs. For transgenic varieties there are also costs for conforming to biosafety and health regulations. Maredia, Byerlee & Maredia (1999) provide a cost-benefit framework for analyzing investments in biotechnology for markets of varying sizes that includes both investment costs and the costs of implementing regulations (biosafety and IPR).

4.1 Defining complementary assets

Both public and private sectors have specific skills and assets that should provide the potential for alliances that exploit complementarities between them. Table 5 shows some potential assets of public and private sectors at both the national and international levels.

Public-sector assets include germplasm and evaluation networks, local knowledge, applied breeding skills and infrastructure, access to a seed delivery system, and public-sector extension. Global life-science companies have assets in the form of biotechnology tools and genes and access to international capital markets. Even public confidence in a research organization or firm may be considered an asset. In the case of biotechnology, global companies are sometimes perceived negatively by the public, while many public-sector organizations enjoy positive perceptions. On the other hand, the private sector may have assets in terms of flexibility in decision making that speeds up R&D.

One of the major bargaining chips available to the public sector is access to and knowledge of germplasm and associated evaluation networks in developing countries. In the past, the national and international plant breeding systems depended on free access to germplasm, both genetic resources as well as developed cultivars. Continued access to genetic resources conserved in gene banks in the CGIAR is guaranteed for the time being under an FAO agreement. However, many NARSs are now restricting the export of genetic resources of domestic origin, and some CGIAR centers are also holding derived genetic materials that may not be freely available in the future.

Clearly, public NARSs will have to develop new strategies that balance the gains from continued free flows of germplasm against the potential to use this germplasm, especially locally-adapted materials, as a bargaining chip (Falcon, 2000). The value of their germplasm and associated knowledge is being enhanced by rapid advances in functional genomics, advances that require access to and knowledge of the genetic diversity available in public research organizations (see Appendix 1). In any event, the use of MTAs to transfer germplasm, research materials, and data is now becoming standard practice in public research organizations.

In developing countries public-private complementarity in terms of assets is the reverse of the situation in industrialized countries—it tends to be with the private sector upstream (knowledge, tools, technologies) in the technology chain, and the public sector downstream (adaptation and delivery). However, there are some advanced laboratories in the developing world where the public sector may have complementary upstream skills, akin to the case in the industrialized countries (e.g., the Novartis alliance with the University of California, Berkeley)¹⁰. These advanced public research institutes may have bargaining chips in the form of molecular tools that they themselves develop. This underlines the importance of public research organizations developing capacity to protect their IP, even if income generation is not the primary objective.

4.2 Segmenting markets

Market segmentation is one way that public and private sectors might exploit their asset complementarities, creating alliances in which the public sector serves resource-poor farmers and leaves commercial farmers to the private sector. In principle, the public sector may be able to negotiate non-exclusive licenses for technology use at no or low cost in certain markets—marginal areas, resource-poor farmers, and orphan crops—that are not of interest to the private sector but where it may enhance the public relations image of private firms. The same technology would be prohibited under the license from being commercialized in other 'more market-oriented areas'. A reasonable goal for the public sector might be to license a product needed for research and use at zero royalty in noncommercial markets, and at a fair and reasonable price for emerging markets, leaving commercial markets to the private sector.

| Organization | Public sector | Private sector |
|---------------------------|--|---|
| National level | Public NARSs | Local seed companies |
| Key assets | Local diverse germplasm Local knowledge Breeding and evaluation programs and associated infrastructure Access to delivery system including extension Upstream capacity [Type I NARSs only] Mostly positive public image | Local knowledge Breeding programs and infrastructure Seed delivery system Marketing network |
| Regional and global level | International CGIAR Centers | Global life science companies |
| Key assets | Diverse germplasm Breeding programs and associated infrastructure Global germplasm exchange and evaluation networks Economies of market size [Upstream capacity in a few centers] Mostly positive public image | Biotechnology tools, genes, know how Access to capital markets Economies of market size Skills in dealing with regula- tory agencies Flexibility and speed in deci- sion making |

Table 5. Assets of Public and Private Sectors in Agri-Biotechnology Research*

¹⁰ At the initiative of the University of California, Berkeley, an agreement has been signed with Novartis that provides financial support to the university to carry out basic research that it chooses, with Novartis retaining the first right to license any useful discoveries.

Segmentation of markets must be decided on a case-by-case basis. Logically it would be desirable to differentiate them by farmer type but this raises practical difficulties. Accordingly, various 'proxy' criteria have been used for market segmentation, including the type of crop, specific varieties, regions, trade status, and country-income level. Table 6 provides examples of how these criteria have been employed in practice in several public-private licensing agreements.

Although market segmentation is a conceptually appealing way for the public sector to gain access to proprietary technologies, there are major practical hurdles to overcome. First, many developing countries have a growing potential private market for technologies and for market segmentation to be effective in larger countries it must be *within* as well as across countries—a much more difficult legal and administrative challenge. Second, technology frequently spills over, often in unexpected ways, to other regions and farmers, and the containment of the IP to the market in question may be difficult. Third, competing firms may gain access to the technology for use in other markets where the IP is not protected, reducing the incentive for private firms to license their materials. Finally, issues beyond IP, such as responsibility and liability for risks incurred are becoming important in gaining access to technology for non-commercial markets.

In practice market segmentation often requires intense negotiation, the development of trust between partners, and the capacity to enforce agreements on markets. The result will generally require compromises that introduce imperfections into market segmentation. A good example in agriculture is the negotiation of the copyright associated with the Essential Electronic Agricultural Library (www.teeal.cornell.edu), whereby the full text of 130 copy-righted agricultural science journals is made available on CD-ROM free of royalties to qualifying countries, based on per capita income level¹¹. Under the agreement which took some years to negotiate with all publishers, some countries in a region may be excluded, while neighboring countries, relatively rich research organization such as an international agricultural research center, or a country affiliate of a global life science company are eligible. Finally, some low-income countries, such as India and China, are excluded, apparently because publishers did not feel they could enforce contracts prohibiting further copying.

| Criteria for segmentation | Example |
|---------------------------|--|
| Crop and region | The Monsanto and Kenyan Agricultural Research Institute agreement for a transgene for control of African sweet potato virus disease allows unrestricted use in sweet potatoes in Africa (Wambugu, 1996). |
| | Insect resistant maize with proprietary technologies from Novartis is being trans- ferred from CIMMYT to Africa but cannot be used outside of the region. |
| Variety | The transfer by Monsanto of genes for virus-resistant potato is restricted to selected varieties of potatoes predominantly grown by small farmers in the central part of the country (Qaim, 1998). |
| Country income level | IRRI negotiated the rights for use of a stem borer resistance gene for rice from Plan- tech for all developing countries, as defined by the UN. |
| Trade status | In Southeast Asia the transfer of genes in papaya provided by Zeneca for delayed ripening and for virus resistance by Monsanto is license free for production for the domestic market, with the right to negotiate a commercial license for export production (ISAAA, 2000). |

Table 6: Examples of Different Types of Market Segmentation

¹¹ However, organizations in qualifying countries must pay costs to cover the compilation, updating, and distribution of the CD-ROMs.

Market segmentation will become more common and will succeed best where there are few IPs and owners involved, where non-commercial markets can be sharply delineated by region, and where it will be easy to exclude spillovers to non-targeted markets. However, the public sector will need to be realistic about what can be achieved *free* of royalties—the strategy to date—and be prepared to consider payment of *reduced royalties* to maximize access to appropriate technologies.

5. Policy and Institutional Options to Facilitate Technology Transfer

The ultimate aim of public policy should be to promote "access to the most advanced beneficial technologies available on the best available terms" (Barton, Lesser & Watal, 1999, p. 15). Various policy and institutional options may facilitate both public and private R&D investment and payoffs as well as alliances among them. These options are discussed below at several levels of decision-making research institutes, national, regional, and global—noting the relevance of each to the NARSs' capacity level.

5.1 Options for individual research institutions

At the level of individual research institutes, the main challenges to accessing technology are priority setting, establishment of international alliances, management of IP, and capacity development.

5.1.1 Strategy formulation and priority setting

Many public research institutes have established biotechnology programs that are "tool driven" but that lack a clear strategy and set of priorities. Reviews of program content show that few programs have identified their strategic niche in an often complex national and international market. Key challenges for NARSs are to establish the comparative advantage of the public sector and identify target populations and priority traits to meet the mandate of the institution (Hossain et al., 2000). Recent examples of priority setting in biotechnology research promise to provide more rigor to program formulation (Braunschweig, 2000). Others have argued for more demand-driven approaches to priority setting that use participatory methods to identify priority problems for which biotechnology offers cost-effective solutions (Spillane, 2000).

Complementarity with the private sector needs to be a central criterion in priority setting for public research organizations. In the early stages, public-sector support is often the key to private sector entry into the market (Pray & Fuglie, 2000). However, once the private sector is established, the public sector is often reluctant to withdraw, and in many cases becomes a competitor. This may be justified under certain conditions to maintain a competitive seed market in a situation of a potential monopoly supplier, but in many cases, such as hybrid seed, the public sector has continued to carry out such research well beyond any justification on these grounds.

5.1.2 International alliances

All public NARSs will have to develop international alliances, both public and private, to access technology. The number of international alliances with the advanced public research institutes in industrialized countries is increasing, but these have usually not been driven by the priorities of the developing country institute (Cohen, 1999). An exception in this regard is the alliance that EMBRAPA in Brazil has formalized with USDA. At EMBRAPA's initiative, several Brazilian scientists have been based in USDA to facilitate the exchange of technology and collaborative research (Lesser et al., 1999). After significant delays due to difficulties in negotiating IP issues, the alliance appears to be working well, and other institutes in Latin America are now giving attention to such alliances, usually with initial support from donor funding.

Alliances between developing country research institutes and private firms have also been developed but usually for very specific technologies. Most of these alliances have been brokered through intermediary organizations. Both ABSP and ISAAA have facilitated alliances between public NARSs and multinational companies (e.g., the Pioneer and AGERI alliance in Egypt discussed above) (Lewis, 2000; ISAAA, 2000). Some NARS have developed bilateral alliances independently of intermediaries such as the alliance between PhilRice (the public sector rice research organization in the Philippines) and a biotechnology company for genomics research (Appendix 1). However, cultural differences between public and private sectors and a lack of IP and business management and negotiating skills in public sector-NARSs are major hurdles for these types of alliances.

5.1.3 Capacity to negotiate and manage IP

Most public research institutes in developing countries lack even minimal capacity in IP management. Increasingly, public research institutes will have to develop their own IP policies and management capacity with a combination of legal, business, and technical knowledge consistent with market size and costs (Lesser et al., 1999). Policies should clarify institutional roles, identify proprietary technologies, secure ownership of assets, and guide management of IP, technology transfer and marketing of IP (Cohen et al., 1999). To become effective, relevant changes in IPR policy must be absorbed into the institutions' internal culture (Sampaio & Brito da Cunha, 1999). This usually requires some type of IPR committee or unit to guide policy formulation and implementation. Large research institutes, such as ICAR in India and EMBRAPA in Brazil, have established special IPR units and formulated policies for obtaining patents for their own IP and for negotiating contracts and transfer agreements with other research organizations, public or private (Sampaio, Brita da Cunha, 1999). Part of the responsibility of these units is to build capacity in IP and negotiation at all levels-scientists, science managers, and policy-makers. Public-sector research systems will also need to develop strategies for determining the profile of IP use and for negotiating a satisfactory arrangement with the various owners in different countries. Finally, an important part of negotiating IP agreements with the private sector will be transparency and accountability, which ensures that public organizations are operating in the public interest. Public organizations must be prepared to disclose full details of such agreements.

5.1.4 IP policy on own inventions

While IP issues initially arise when accessing others' technologies, public research institutes with significant biotechnology research capacity must also establish a policy for protecting their own IP. The policy must promote the overarching goal of public institutes to maximize the benefits of their investments for society at large. This requires policy guidelines on the following types of decisions (Barton, Lesser & Watal, 1999):

- Which inventions should be freely released to the public?
- Which inventions may be most efficiently brought to the user through the private sector and how can this be achieved in a transparent and equitable manner?
- Which inventions can be a potential source of income?
- Which inventions and assets can be used as "bargaining chips" for cross licensing?
- Which inventions need IP protection in order to keep them in the public domain?

The costs of IP protection and enforcement will also be a key factor in decision making. These will vary enormously from relatively low cost protection in local markets through plant breeders' rights to expensive patent protection in regional and global markets that requires extensive data searches and multiple patent filing. Experience suggests that income generation should *not* be the primary motivation for IP protection in the public sector, since only a handful of patents earn significant revenues. Instead, defensive protection to keep innovations in the public domain and to use them as bargaining chips are likely to be the major reasons for IP protection of public sector innovations.

5.2 Options at the country level

5.2.1 Development of a national biotechnology strategy

While many countries are investing in biotechnology, these investments are often very supply driven and in larger countries, fragmented. In particular, there is often little linkage between agricultural research institutes and general science institutes and universities who conduct much of the research on both agricultural and medical-related biotechnology (Janssen, Falconi, & Komen, 2000). As a result, public research institutions, even within a country, are not exploiting complementarities and economies of size. There is also a need for better collaboration between biotechnology institutes and those involved in crop breeding to ensure that biotechnology research responds to priority demands, and when tools and products are developed, they are quickly used to improve varieties for farmers. Options for improving synergies include participatory formulation of a national science and technology policy with wide "ownership," as well as establishment of competitive funds that favor proposals based on partnerships of research organizations with complementary skills and assets.

5.2.2 Centralized technology transfer offices

In order to reduce costs, some countries are moving toward centralized national technology transfer and IP services to seek out and negotiate appropriate tools (Maredia, Erbisch & Sampaio, 2000). A centralized service at the national level can facilitate external negotiations and provide support to institutions that lack the needed skills. Technology transfer offices could also aid in harmonizing MTAs among public organizations, thereby reducing the transaction costs of transferring IP within a country (Lesser et al., 1999). For example, Indonesia has established a central office for technology transfer to help negotiate access to technologies of value to Indonesian agricultural research programs. Likewise the CGIAR has recently developed a Central Advisory Service to support the CGIAR centers in developing data bases on IPR expertise, patents and IP issues, and in assisting them with IP negotiations. Centralization may also provide increased bargaining strength in negotiations on technology access. The main risks of centralization are the distancing of IP management from research decision making and the potential to create another bureaucratic hurdle for scientists.

5.2.3 Ensuring an enabling regulatory environment

An enabling regulatory environment is critical for entry of the private sector and for public sector access to technologies. Most developing countries still do not have adequate biosafety and IPR regulations in place, although most are formulating regulations as required by international treaties. For small countries, the costs of establishing adequate analytical capacity for decision-making and enforcing regulations may be large in relation to benefits. However, effective implementation of the recent Cartegena Biosafety Protocol of the Convention on Biological Diversity will require that all sovereign countries have the capacity to make decisions about the importation of transgenic products and seeds.

In addition, most countries have rigid and outdated regulations governing the import of germplasm and the release of varieties that are based on public sector needs. These regulations prevent the entry of both local and global private firms. Other types of incentives for the private sector include tax concessions for R&D investments, which are widely used in industrialized countries and some developing countries (Pray & Fuglie, 2000).

5.3 Options at the regional level

5.3.1 Regional research consortia

Individual public research organizations in small and medium-sized developing countries are at a comparative disadvantage in accessing biotechnology products because of the substantial economies of size in biotechnology research, their small market size, and their weak bargaining position with respect to large private firms. Yet regional public NARSs will often have similar targets, needs, and assets, which provides an incentive to pool resources. One approach is to form consortia of public NARSs within a region, or even across regions, in order to access biotechnology knowledge, tools, and products. For example, NARSs may have a common interest in gaining FTO for a specific tool essential for the delivery of their products.¹² NARSs may be in a better position to gain access and/or cross license if they negotiate as a consortium or group. Furthermore, costs can be shared. In other cases, a consortium of strong NARSs could pool resources to "design around" a component proprietary technology. A regional consortium could also form the basis for the free sharing of germplasm products and biotechnology tools among public NARSs within a region.

There are thus strong reasons to formalize regional consortia in biotechnology. Regional collaboration is already occurring through programs such as the Asian Rice Biotechnology Network (ARBN), the Asian Maize Biotechnology Network (AMBIONET) and the Latin American Biotechnology Network (REDBIO). However, to be able to handle sensitive IP issues and negotiate with the private sector, such networks will need to upgrade to a consortium with a legal basis and a strong but small central unit to negotiate and even hold IP on behalf of consortium members. This poses a much greater and as yet untested challenge.

5.3.2 Regional regulatory frameworks

Successful regional cooperation in IPR, biosafety, food safety, variety release regulations, and seed laws would allow private firms to reap economies of size by operating in larger markets, while also considerably reducing the costs of biosafety approval and IP transactions for both private and public research organizations and for regulatory bodies. One approach used in the EU is harmonization of member-country regulations combined with a system of reciprocal recognition of plant varietal protection and varietal release for all countries in a region. Another approach that may be even more cost effective would be to establish centralized regional regulatory offices to serve all member countries in a region. In Africa, for example, regional patent offices allow centralized patent registration. These arrangements will be especially relevant for regions made up of small and medium-sized countries, many of which will be adopting plant varietal rights as well as biosafety and food safety rules in the near future. The emerging regional agricultural research associations that are now active in all regions could play a pro-active role in facilitating such initiatives.

5.4 Options at the global level

At the global level, there are many institutional options for donors and international organizations to facilitate access by developing countries to knowledge, tools, and technologies of high priority to poor producers and consumers. Some of these might be considered international public goods that have wide global spillovers, but many options relate more to what are generally considered private goods that require global interventions to correct various types of market failures. Global options include support for the CGIAR, establishing a global fund, and developing tools kits and centralized data systems.

¹² This is especially so where NARSs in a region have similar capacities. However, the interests of NARSs of different capacities may reduce incentives for regional collaboration, especially since Type I NARS are in a strong negotiating position as tool developers and Type III are essentially importers of the technology.

5.4.1 Support to the CGIAR

Although a relatively small investor in biotechnology, the CGIAR is a potentially important 'bridge' between advanced private and public research organizations and public research organizations in developing countries, especially smaller NARSs. Each of the crop and livestock CGIAR centers have established a capacity in biotechnology, usually downstream in the R&D chain but with sub-optimal collaboration among them. The recent review of plant breeding and biotechnology in the CGIAR has recommended sharply increased efforts to communicate, collaborate, and share tools and expertise among the CGIAR centers (Technical Advisory Committee, 2000). Given economies of size in biotechnology research and the increase in spillover potential among crops with the application of genomics and bioinformatics, the question arises as to whether the CGIAR should be centralizing *the conduct* of some of its biotechnology research either at the global level or at the regional level. Even with centralization, it is not clear what research should be undertaken in the CGIAR, what should be done in partnership with non-CGIAR centers, and what should be contracted out. Another option would be to *centralize funding* of selected activities, perhaps on a competitive basis, at the same time giving preference to funding partnerships among centers and with others to deliver specific tools and products that have broad applicability.

Much of the technology and many of the tools used in the CGIAR, have been acquired from the private sector. Several CGIAR centers have also negotiated partnerships with the private sector using their own tools and products as bargaining chips. However, the CGIAR centers lacked experience with proprietary technologies and have been 'learning on the job' with respect to IP management. In many cases, formal agreements had not been obtained for research or the commercial use of technologies arising from application of the tools (Cohen et al., 1999).

Many CGIAR centers are experimenting with market segmentation approaches, and some have been able to obtain licenses to allow selected countries or regions (and sometimes all developing countries) to freely use the tools and the resulting products. CGIAR centers do not release products directly to farmers, but to NARSs, and various and sometimes complex arrangements are possible for handling IP. IRRI, for example, has proposed a model for the transfer of IP traits to locally-adapted germplasm built around a triangular agreement among:

- 1. the public germplasm providers (in this case IRRI),
- 2. the owner of the IP trait (usually private), and
- 3. the public NARSs with a mandate to release and deliver improved varieties to users.

The model uses a license or MTA *for research* between IRRI and the IP owner, on the understanding that a NARS that wishes to use products of the research would obtain a license agreement *for use* directly with the IP owner(s) in ways that provide the best choices for its farmers. Similar principles are also being developed for new initiatives in functional genomics, described in Appendix 1 (Fischer et al., 2000).

One major disadvantage of this approach is the cost and skills needed for each NARS to negotiate with the IP owner. Regional consortia and other collaborative arrangements may be a more cost-effective way for NARSs to negotiate such agreements. Alternatively, where the countries served by the CGIAR center are mainly made up of non-commercial users in Type III NARS, it should be possible for the CGIAR center to negotiate the FTO for research and use for all countries being served (e.g., for centers operating in Africa).

Similarly, for products developed by the CGIAR, various options for IP management are also possible:

- The CGIAR center might take out a defensive patent and make the product freely available
- The NARS or a consortium of NARSs might hold patents on behalf of the CGIAR center and license as appropriate to other public and private organizations.
- The CGIAR center might grant the private sector in a country exclusive rights, subject to approval by the relevant policy making body in that country.

IP strategies of CGIAR centers will necessarily vary according to the target region and crop. Centers such as IRRI that mostly target strong NARSs where there is a growing private sector presence will necessarily adopt very different strategies to centers that mostly target weaker NARSs.

5.4.2 Global funding through a donor consortia

New and innovative global approaches to forming partnerships between the private and public research systems for application in developing countries are needed (Pinstrup-Andersen & Cohen, 2000). Although donors allocate considerable resources for biotechnology research for developing countries, this effort is fragmented and does not exploit potential synergies. One approach to engaging the private sector in developing technologies primarily for use in noncommercial markets would be for a consortium of donors to establish a fund to competitively contract the private sector to provide high priority technology (Sachs, 1999). The consortium would establish priority tools and technologies and then request bids to develop them, perhaps on a regional basis. Universities and other advanced research organizations in the public sector of the industrialized countries and developing countries might also be asked to join such alliances and pledge part of the costs of delivering the product to users after the technology has been developed. Such an arrangement could be especially appropriate to access key enabling technologies for the so-called "orphaned" crops. The same fund could also hold the IP of resulting products, which would be freely available in non-commercial markets, but might be licensed for earning royalties in commercial markets.

5.4.3 A tool kit for public institutions

A related proposal would be the formation of a public-sector consortium to develop a basic tool kit for the application of biotechnology in developing countries (Fischer, 1999). The consortium would negotiate a license for some components of the tool kit for use by its members. Others components of the tool kit might be 'designed around'—that is, strong NARSs or a consortium of NARSs would invest to develop their own approaches based on non-proprietary technologies or technologies with which they have full FTO. A further extension of this concept would be to encourage a coalition of patent holders to assemble a tool kit to allow one off licensing in order to reduce transaction costs to technology acquisition (C. Spillane, pers. comm.).

5.4.4 IP information systems and clearing houses

A major reason for market failure in the international transfer of proprietary technology is the high transaction cost of patent search and registration. There is an obvious need for international collaboration to establish IP information systems and clearing houses. Such a system could greatly reduce the cost to developing countries of patent searches both for accessing technology and for patenting their own inventions. CAMBIA, for example, envisions an internet-based patent database that will enable a user to easily access and analyze published patents and patent applications from many countries. (www.cambia.org/main/ip_stratgr.htm). Similar data bases could be established for public domain technologies in order to make these more readily available in developing countries (Spillane, 2000). These information systems might eventually evolve into clearing houses that offer 'one-stop' brokerage services for buying and selling IP.

6. Conclusions: Strategies for NARSs of Different Capacities

Although biotechnology research is concentrated in the "north," research aimed at poor producers and consumers in developing countries is growing, led by the public sector. The total investment of over US\$ 200 million by donors, the CGIAR, and developing country NARSs in agricultural biotechnology is

significant and probably several times larger than private R&D directed at developing country farmers (although small in relation to that invested by private companies in industrialized countries).

This review has been framed within the wide variation of NARSs' capacities in biotechnology research and in the characteristics of the markets in which their products will be used. Table 7 summarizes the very different options and strategies for the strong Type I NARSs and the large group of Type III NARSs that currently have no capacity. Strong NARSs are already moving to develop upstream capacity in tool development and genomics, and potentially these NARSs could become major players in the global market place. Although they need to improve skills in IP management and negotiation, they will be able to make deals directly with private companies to access technologies and for joint ventures, using both their germplasm assets and their own proprietary tools as bargaining chips.

At the other extreme is the large number of relatively weak NARSs with no current capacity. All but the smallest of these countries need to develop a core capacity to seek out, import, evaluate and regulate appropriate technologies from abroad. This core capacity would consist of a nucleus of scientists and policy analysts that can closely monitor developments on the global scene, set a few well-defined priorities for the country, and tap tools and technologies that meet those priorities. This capacity will also be required to meet obligations in recent international treaties. Clearly, these NARSs can gain most by regional approaches both in research capacity and in regulation. They will also need to develop alliances with intermediaries, especially the CGIAR. On the other hand, these countries enjoy a major advantage in exploiting segmented markets to obtain products from the private sector free of royalties, and in some cases, in unilaterally accessing technologies.

| Issue | Type I NARSs that already have strong biotech capacity | Type III NARSs with no current capacity in mo- lecular biology |
|--|---|---|
| Public sector research capacity | Invest in upstream capacity for tool development, and to design around key components Contribute to global structural and functional genomics consortia and data bases Define and assert 'ownership' of selected biological assets for specific traits | Develop minimum capacity to seek out, evaluate and regulate appropriate technologies from abroad Define and assert 'ownership' of selected biological assets for specific traits |
| Private sector research | Provide favorable regulatory environment on technology importation, protection, and release consistent with societal norms on risks. Revisit priorities of public sector to ensure complementarity with the private sector | Provide favorable regulatory environment on technology importation and release, preferably through harmonized or centralized regulations at the regional level, and reciprocal agreements among countries in the region |
| Public- private partner- ships | Negotiate commercial licensing agreement directly with private companies for accessing tools and technologies for commercial and emerging markets Bargain for royalty free license for non-competitive market Develop and protect own IP products and for use as bargaining chips in joint ventures | Obtain access to products under royalty-free li- cense, often through intermediaries such as re- gional consortia and the CGIAR |
| Regional/ international alliances | Develop partnerships for upstream re- search with advanced public and private research organizations and with the CGIAR | Promote regional networks and consortia to borrow technologies Develop alliances with CGIAR, and multilateral initiatives to act as intermediaries |

Table 7: Summary of main policies and strategic options for NARSs of differing capacities^{*}

^{*} Type II NARSs that are developing biotech capacity will be intermediate between the two extremes depicted in this table.

For most NARSs and especially for those which are developing capacity (i.e., type II), innovative mechanisms, such as consortia, are needed to pool public-sector resources to buy, develop, and license priority technologies. Many needed tools will be common across crop and geographic boundaries, providing opportunities for consortia or networks to concentrate public resources to solve a common problem. While many networks are moving toward such collaboration, the increasing importance of IP requires that they establish a more formal legal and business base.

For all NARSs, strengthening their funding and institutional base for public R&D will be critical to address emerging food security and environmental challenges and especially to tap global advances in science that can address these problems. All NARSs are being challenged to increase investment in biotechnology capacity in a time of stagnating support for public R&D. The public sector must reexamine its targets to ensure that it complements and does not 'crowd out' potential commercial markets. For strong NARSs, resources to enhance their capacity in biotechnology can be obtained in part by gradually turning over much of the applied plant breeding in favored environments to the private sector. This requires an appropriate enabling environment for private R&D, and well-defined strategies and priorities for the public sector. Of particular concern is the large number of relatively weak NARSs with no capacity in molecular biotechnology and who are struggling to maintain plant breeding or varietal testing programs. For these NARSs, it will be risky to develop a minimal capacity in biotechnology at the expense of other applied research areas, and increased public investment in R&D combined with regional approaches is the only way forward.

Public research organizations have to redefine their role and upgrade their expertise in a changing world of new science, and new norms about the ownership, sharing, and use of that science. Public research organizations at different levels—national, regional and international—will have to develop innovative mechanisms to work with the private sector to access needed tools and technologies, recognizing the complementary goals, skills, and assets of each side. The public sector has critical assets in the form of germplasm and associated biological knowledge that are increasingly important in the new science of genomics. However, to fully exploit these assets, the public sector must develop a capacity in IP management and in business skills and clearly identify the value of its own assets in negotiations. Market segmentation is likely to be a key element in public-private negotiations. And yet although most public-private alliances to date have been based on free access to proprietary technologies for non-competing markets, this is unlikely to be a sustainable strategy. The public sector realistically needs to think in terms of royalty payments (hopefully discounted) to the private sector in order to maintain a flow of up-to-date and relevant tools and technologies.

Finally at the global level, there are a variety of options for innovative partnerships among donors, multilateral agencies, the private sector, and NARSs to bring fragmented resources to bear to solve priority problems that transcend national and regional boundaries. International leadership is needed to explore the establishment of an international fund to bid for the supply of key enabling technologies that are especially relevant to poor producers and consumers. In addition, the formation of global public-private alliances and international agreements will be critical to ensure that the current explosion in genomic information can be tapped to solve the problems of poor producers and consumers.

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Appendices

1. Developing countries and international collaboration in genomics: the case of rice

The emerging science of genomics, which promises to take center stage in modern biotechnology research, illustrates how these various partnership arrangements might be developed in innovative ways that allow the sharing of information and technologies for maximum societal benefit. The rice genome, the smallest and simplest among major food crops, will be one of the first to be completely sequenced (mapped) through the efforts of the International Rice Genome Sequencing Project (IRGSP).¹³ It is significant that all contributors to this sequencing effort are committed to immediate release of the sequence data to the public.

To exploit this information will require detailed genetic and phenotypic analyses to identify and understand functions of specific genes, much of it to be carried out in field conditions—so called functional genomics. A completely sequenced and freely accessible rice genome promises an enormous pool of genetic markers and genes for rice and other cereal crops through marker-assisted selection or genetic transformation.

Both public- and private-sector resources are needed to exploit the potential offered by genomics. Scientific expertise is required from several disciplines as well as access to diverse germplasm, molecular tools, and large capital investment. Public-sector research organizations, including the CGIAR, have a large investment in biological resources in plant breeding programs and a long and skilled history of understanding biological functions through a variety of evaluation networks. These biological and scientific resources will become increasingly important in gaining knowledge about the function of genes. 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 to manage the large databases required.

The goal of a such a collaborative agenda for gene discovery would be to achieve a fair balance between the "freedom of access" to new knowledge for the public sector and IP protection for the private sector to recoup its investment in innovation. Fischer et al. (2000) have proposed a collaborative agenda between the public and private sectors for trait discovery in rice, depicted in Figure 2. The essential inputs are the genetic resources and biological expertise, which are largely in the public sector (G in Figure 2), and DNA arrays and sequence information, which are largely in the private sector (P). Gene functions would be identified through a collaborative effort of the public sector, especially IRRI and other strong NARSs that have the required germplasm diversity, and the private sector, which would contribute molecular analysis techniques and gene product development. The major outputs would be gene discoveries that could be employed in transgenics and molecular markers. The pattern of property rights envisioned in the collaboration is that the biological materials will be made available to the public and private sectors under an MTA, the recipient (i.e., private sector) is permitted to obtain patents on genes discovered through use of the material, and the recipient is required to make rights under those patents available at a reasonable royalty for application in the developing world (and at zero royalty for use in noncommercial markets). The large number of molecular markers expected to be derived from the work would also be made freely available to plant breeding programs for food crops in the developing world.

The public NARSs also have opportunities to develop similar alliances with the private sector to facilitate the mining of traits from their local materials. Many small private companies have a special interest in particular traits for application outside of industrialized countries. An example of this approach is a collaborative agreement between PhilRice (the public-sector rice research institute of the Philippines) and a U.S. private agricultural biotechnology company. The research program focuses on the production of mutants to be used for screening for specific traits in rice that will have application in rice and in other crops. Under the research

¹³ This is a public, international effort coordinated by the Japan Rice Genome Program (<u>www.staff.or.jp/rgp/rgp/rgpintro.html</u>). The number of participants in the IRGSP is large, and includes, in addition to Japan which spearheads the program, the rice-growing countries of China, the province of Taiwan, India, Korea, and Thailand, as well as France, the United King-dom, and the United States. Recently, Syngenta announced the completion of the rice genome map and pledged that the information will be made available for the benefit of subsistence farmers in developing countries, free of charge.

agreement, the company will provide funding for the research program and agrees to transfer novel technologies to PhilRice and provide training to PhilRice scientists. In return, the company will receive information on the field screening (phenotyping) of large numbers of mutant materials. Technologies or products arising from the research program will be available to the company on a worldwide basis and freely accessible to PhilRice to enable it to address issues that are of priority to the Philippines (L. Sebastian, pers. comm.).





2. Useful web sites on agri-biotechnology policy and development¹⁴

AfricaBio (NGO) www.africabio.com

AgBioWorld www.agbioworld.org

Biotechnology Information Network and Advisory Service (BINAS) www.binas.unido.org/binas/binas.html

CABI AgBiotechNet www.agbiotechnet.com

Center for the Application of Molecular Biology to International Agriculture (CAMBIA) www.cambia.org

Information Systems for Biotechnology www.isb.vt.edu

Information Systems for Biotechnology www.nbiap.vt.edu

International Center for Genetic Engineering and Biotechnology (ICGEB -Biosafety) www.icgeb.trieste.it/biosafety

International Service for Acquisition of Agri-Biotech Applications (ISAAA) www.isaaa.org

ISNAR Intermediary Biotechnology Service (IBS) www.cgiar.org/isnar/ibs.htm

OECD-Biotrack Online www.oecd.org/ehs/projects.htm

Strategic World Initiative for Technology Transfer (SWIFTT) <u>www.swiftt.cornell.edu</u> (as of August 2001)

Technical Co-operation Network on Plant Biotechnology in Latin America and the Caribbean (REDBIO/FAO) <u>www.rlc.fao.org/redes/redbio/html/home.htm</u>

UNEP-International Registry on Biosafety www.eurospider.ch/BATS/index.html

USAID Agricultural Biotechnology Support Project (ABSP) www.iia.msu.edu/absp

World Intellectual Property Organization (WIPO) www.wipo.int

¹⁴ K. Maredia (pers. comm.).

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