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Public-Private Partnerships for Efficient Proprietary Biotech Management and Transfer, and Increased Private Sector Investments

A Briefings Paper with Six
Proposals Commissioned by
UNIDO

Anatole F Krattiger

*bio*Developments LLC (International Consultants), USA/Switzerland
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Executive Summary and Main Proposals ¹

Public-Private Partnerships for Efficient Proprietary Biotech Science Management and Transfer, and Increased Private Sector Investments.

A Briefings Paper with Six Proposals Commissioned by UNIDO ²

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Introduction and Objectives: Evidence is fast emerging that biotechnology will have far reaching consequences on every aspect of our lives. The early applications in agriculture have already led to significant improvements in farm productivity, income enhancement, reduction of toxic chemical insecticides, enabled more flexible farm practices, and water conservation through zero-till agriculture. The private sector has been the main investor, partly because of the high level of patent protection that can be obtained with modern biotech. Worldwide, companies invest perhaps as much as US\$2.5 billion annually in plant biotech R&D which far exceeds public sector investments; developing countries invest less than 5% of that total and this is unlikely to increase in the near term. Opportunities must therefore be created for developing countries by building upon private sector investments already made. This paper discusses principal elements of biotech transfer, reviews factors encouraging/discouraging its transfer, and proposes six initiatives that could be launched regionally or even globally to stimulate North/South and South/South transfers. The major contribution a regional approach could make is at the level of accessing intellectual property and scientific capacity by leveling the playing field.

Technology Transfer and Biotechnology Management: Biotechnology has two principal applications in agriculture, namely increases in breeding efficiency and in crop/farm productivity. Each of these require different strategies for tech transfer. The technology also has two components: intangible “knowledge” (intellectual property; IP) and tangible “materials” (technical property; TP). This distinction is critical in IP strategies and has significant trade implications. Since the adoption of new technologies initially benefits the early adopters most, and since economies in a region are closely linked, technological change in one country affects neighboring countries. Regional collaboration and coordination, therefore, is an essential strategy for agricultural growth and even regional political stability.

¹ Krattiger, A.F. 2002. Public-Private Partnerships for Efficient Proprietary Biotech Science Management and Transfer, and Increased Private Sector Investments. A Briefings Paper with Six Proposals Commissioned by UNIDO. *IP Strategy Today* No. 4-2002.

² The Forum was held in Montevideo, Uruguay, from 28-30 March 2001.

I am deeply indebted to many friends and colleagues from around the world for constructive comments, inputs and suggestions that led to this briefing paper and helped my thinking and understanding. Particular thanks are due to William H. Lesser, R. David Kryder and Andrew Hamilton who contributed significantly to the thinking in the development of elements of some of the proposals here. I am also pleased to acknowledge UNIDO's support and would particularly like to thank George Tzotzos for his constructive comments on an earlier version of this manuscript.

Biotech is knowledge-based and hence is a non-consumable good. The technology is ideally suited to be traded and can relatively easily be adapted to local environmental conditions. But it is inherently cultural because biotech essentially is “ideas” which both shape the technology and is shaped by technology. The introduction of biotech, therefore, requires communication relating the technology to local cultural and societal values; much can be learnt from the recent experience in Europe.

Companies entering international markets go through a two tiered decision process, choosing between exports of goods and production in the target country; and between foreign affiliate or other business forms for local production (license, joint venture). Licensing is an intermediate form of transfer and has the benefit of affiliation with established local partners and less investment risk. Disadvantages are limited control and less quality assurance. Donations for humanitarian purposes face similar constraints: the risk of loss of control of the technology; potential negative public relations if the products disseminated do not meet high product quality standards or if regulatory procedures are not followed; and longer term risk of creating competitors. But the rewards for humanitarian transfers are potentially significant: delegation of leadership; encouragement of regulatory development; increase in national capacity; creation of goodwill based on trust and understanding; and public perception.

Differences between private and public sector’s approaches to IP management is slowing the dissemination of biotech. However, the proprietary nature of biotech concurrently is strengthening new alliances (e.g. industry-university and other public-private partnerships) and has led to increased venture capital flows. Strong national IP systems provide greater access to proprietary technologies, ultimately benefiting the farmers and national agricultural economies. Consistent IP policies and professional IP management is a pre-requisite to working with the private sector. The challenge is to set mechanisms in place that assist the various parties in recognizing opportunities for mutually beneficial partnerships. Since any partnership is based on trust, a prerequisite for public-private partnerships is mutual respect of each other’s property. A final aspect of IP management is the need to have freedom-to-operate (FTO) for the IP and TP embedded in the products, particularly if the products are eventually traded internationally.

Constraints in Biotechnology Transfer and Adoption: Tech transfer has been taking place for a long time. What is new with biotech is the extent to which the transferring parties are claiming rights in what is being transferred. This trend is driven by two factors: high capital requirements and the inability—absent the use of law—of a transferring party to prevent pirating once that product has left its control. These risks, of tech transcendent nature, are not new and governments can significantly reduce them through five policy interventions, namely strong IPRs, effective biosafety and food safety regulations, consumer choice, promotional trade policies, and sound public research investments.

Institutional IP management strategies of public and private entities vary significantly for reasons related to R&D capacity, critical mass, cost, legal aspects, strategic objectives, and public opinion. The options available to any type of entity essentially consists of six choices, of which all but option No. 4 require significant additional funds:

1. Invent around current patents (science and research based approach).
2. Re-design product (product development based approach).
3. Convince IP and TP owners to relinquish claims (humanitarian high ground).
4. Ignore all IP and TP (short term perspective; not feasible in global context).
5. Seek licenses for all IP and TP (complex licensing approach).
6. A mix of options 2 to 5 (pragmatic approach).

Criteria and Priorities for New Biotechnology Transfer Support Activities: Conceptually, biotech has the potential to flow relatively freely around the globe, all the more as it is non-consumable knowledge, subject to adaptation for local needs and conditions. In practice, biotech transfer is subject to

multiple impediments and risks. Increased transfers to spur agricultural economic development will require new initiatives and specific actions. In short, what the private sector does not want to do becomes in part a public responsibility; and what the private sector cannot do becomes an opportunity for public policy.

Complex strategy choices are necessary to meet preferred goals and objectives. Conceptually at least, the three basic choices are to leave the matter exclusively to the private sector; to strengthen national public R&D capacity and “do it alone”; or to place priority on an enabling environment encouraging private investments and public/private partnerships. It is argued here that the third option provides most benefits. The proposals in this Briefings Paper were developed with this in mind and building on comparative advantages.

Concept Proposals for Potential Biotechnology Transfer Support Activities: Each proposal in the main document contains an objective, a detailed rationale, a proposed strategy, implementation thrusts, estimated resource requirements and funding options.

Note that the proposals all place emphasis on agricultural biotechnology but most initiatives could, in principle, be extended to animal health, pharmaceuticals, bioprospecting, and access to genetic resources. Within each of the six proposals, individual strategy elements could, to some extent, be implemented in isolation of each other; similarly, certain strategic objectives could be mixed between proposals depending on how the relative merit is viewed. The Regional Biotechnology Forum which convenes in Montevideo (28-30 March 2001) is intended to prioritize the transfer support activities proposed in this paper, all of which are directed towards increasing—directly or indirectly—the competitiveness of the agricultural sector, the agricultural biotech industry, and the underlying R&D capacity in Latin America.

Proposal 1: Encourage Governments to Implement Supportive Policies

Provide an enabling environment for local and international companies to operate competitively in a transparent market by:

1. **Developing a coherent national biotechnology policy** (encouraging public and private R&D and investments; negotiating positions, and meet international obligations).
2. **Providing incentives for R&D** (tax regimes, venture capital tax incentives, other).
3. **Ensuring public awareness at all levels** (communication with the public about the rationale for decisions and the risks and benefits of crop biotechnology).
4. **Establishing effective biosafety and food safety regulations** (transparent regulatory system, science based and meeting international standards).
5. **Enacting IP legislation to establish a regime consistent with legal obligations** (e.g. WTO, providing economic incentives to the private sector, incl. appropriate antitrust laws).

To what degree Latin American countries wish to strengthen their policies in the five principal areas related to biotechnology transfer is a matter for sovereign decision. What is proposed here is that the conference issues a concise statement to be distributed widely to senior policy makers, ensuring that policy makers are both aware of their role and responsibility in biotechnology (and the consequences of their choices) and know the support activities offered by the professional associations. Simultaneously, a follow-up strategy could be pursued with key policy-makers in each country, engaging them in a dialogue, effectively working with the current and future government “champions” of biotechnology transfer.

Proposal 2: Coordinate Biotechnology Communication at the Regional Level

Ensure that policy makers, opinion makers and key decision makers have access to up-to-date authoritative information and knowledge related to the need for and use of biotech applications, based on scientific facts, local cultural and social values, by:

1. **Building communication and information access and exchange** capacity in each of the participating countries, catalyzing local communication input into the strategy.
2. **Preparing documentation and information packages** in various forms to meet the needs of different target audiences (lay public, journalist, ministers, etc.).
3. **Establishing a commodity based technology transfer information network** (related to commodities of regional importance).
4. **Undertaking high profile targeted meetings**, mainly in conjunction with visits of locally recognized world or opinion leaders as independent and credible voices.

Thrust 1 would include compilation of electronic information, diffusion of key publications, fellowships to exchange people and personnel, compilation of the current and potential impact of biotechnology in Latin America, and the organization of specific information diffusion events. Thrust 2 would include the preparation of short fact sheets and their translation into national languages, the preparation of illustrative studies and interviews, and the compilation of major news events and their meanings to the local situations. Thrust 3 calls for the identification of working scientists from each group who will monitor their institution and report on the current situation, and work together with information clearing houses to place their institutional information into a wider concept. Thrust 4 would include short term visits by leading national, regional and international figures to facilitate well informed discussions with various constituencies, television, radio and newspaper interviews, panel discussions at universities and other locations, and meetings with consumer groups and advocates.

Proposal 3: Establish a Regional Brokering Service to Strengthen Public-Private Partnerships

Establish a biotechnology broker service to facilitate biotechnology transfer to and from Latin America, public/private partnerships and national IP portfolio management by:

1. Providing **institutional IP portfolio management services** to public and private entities;
2. Initially **broker biotechnology transfer deals** that meet primarily humanitarian needs in the region, gradually expanding into semi-commercial (and even commercial) deals; and
3. Develop, whenever possible, **capacity building** activities in institutional IP management.

The management of proprietary science, particularly biotech and its transfer is becoming ever more complex. A pooling of resources and expertise at the regional level offers advantages because the specialized skills, contacts and experience required are unlikely to be afforded by public and smaller private entities in the region.

Thrust 1 is related to the need to ensure that institutions professionally manage their own and acquired IP to instill trust and confidence. The service would offer institutional policy and strategy development (e.g. staff policies and employment agreements, publication policy, assignment of ownership of inventions, etc.); institutional IP management services (e.g. FTO reviews, agreements management, internal TP management, compliance monitoring, etc.); technology valuation services (technology and germplasm); and assistance in the protection of inventions (i.e. patenting) and in the marketing of such portfolios. Thrust 2 is related to the need for professional assistance to reduce transaction costs. The broker service would act as a dynamic intermediary between technology donor and recipient; help es-

establish, build and sustain trust among all parties involved; and solve current problems, through in- and out-licensing (e.g. negotiation, Heads of Agreement drafting, etc.); the development of template agreements for wide distribution; and through mediation between parties when they seem to have reached an impasse. Thrust 3 recognizes that biotechnology transfer activities and business development can only be sustained if institutional capacity exists.

Proposal 4: Develop a Regional Biotechnology Investment Service

Provide business investment services to local entrepreneurs, small companies and university researchers to facilitate biotech acquisition and transfer from laboratory to market; leverage official development assistance (ODA) and foreign direct investment, by:

1. **“Marketing” investment opportunities** with potential investors.
2. **Providing sustained quality deal flow**, incl. Private investors, investment advice and management services.
3. **Work with investors for increased participation**, incl. private Inter-American Development Bank (IDB) and national governmental agencies to leverage ODA (and ultimately Foreign Direct Investment; FDI).
4. With time, an **“investment company for development”** could be created as a logical extension of the three thrusts proposed here.

Thrust 1 will lead to business development, the reduction of risks and transaction costs for investors, and reduction in the costs for entrepreneurs to access capital. Thrust 2 is related to the overall unsatisfactory acquisition and licensing opportunities for life science companies in developing countries due to shortage of sound medium-sized (US\$2-10 million) quality deals with indigenous firms, compelling industry to the slow and risky process of development *de novo*. Complications also arise from difficult management re-structuring, lack of trained managers, and the need for technological upgrading. Thrust 3 aims at leveraging increased ODA, recognizing that it plays an essential role in encouraging FDI. The implementation strategy calls for the preparation of a feasibility study and blueprint by a small team of experts and advisory group. A regional service is envisaged that specializes in biotech assistance for local businesses and ventures with multinational companies.

Proposal 5: Create an Integrated IP Escrow Service (Patent Pool)

Provide tech owners, the public sector and the small business community with a convenient and trusted service to exchange IP for humanitarian/semi-commercial needs, by setting up:

1. **a Foundation to hold licenses** and technologies;
2. **a brokering service addressing the humanitarian** and capacity building needs, directly reinforcing Proposal 3; and
3. **a brokering service addressing the semi-commercial** and commercial needs, directly reinforcing Proposal 4.

Thrust 1 is related to liability issues such an entity would face and aimed at risk shifting, and the provision of tax incentives. Thrust 2 is related to the need to first establish a new model and develop the credibility and experience necessary to operate a broader entity for semi-commercial and commercial applications. Thrust 3 directly assists technology owners in the management of their IP and TP. That third entity would also be aimed at increasing the licensing income of technology owners. A parallel in this service exists with the proposed broker service (Proposal 3) but is aimed exclusively at commercial entities.

This service would negotiate in advance with IP and TP owners license terms for the different uses, either for an entire biotechnology product or for individual biotechnology components. In that way, researchers at universities, NARS and the CGIAR, as well as smaller businesses, could determine, in advance, which technologies were available to them and under what terms. This would assure the researchers of the availability of certain component parts and could formulate their R&D plans accordingly. Once established and operating, the IP service could also allow for royalty bearing sub-licensing to small companies in developing countries (and industrialized ones), which could provide technology owners with an added incentive to participate in the service. That would directly impact the efficiency of the Proposals described under 3 and 4.

A full feasibility study would be required that places particular emphasis on investigating the possibility of whether such a patent pool would need to be global or whether it could operate efficiently at the regional Latin American level, different modalities of licensing structures, and institutional issues (strategies, structure, governance, possible affiliation, etc.).

Proposal 6: Elaborate on and Develop Initiatives for Risk Shifting

Minimize risks inherent in biotechnology transfer by providing specific government guarantees (reducing the transfer risk for entities willing to transfer applications) by:

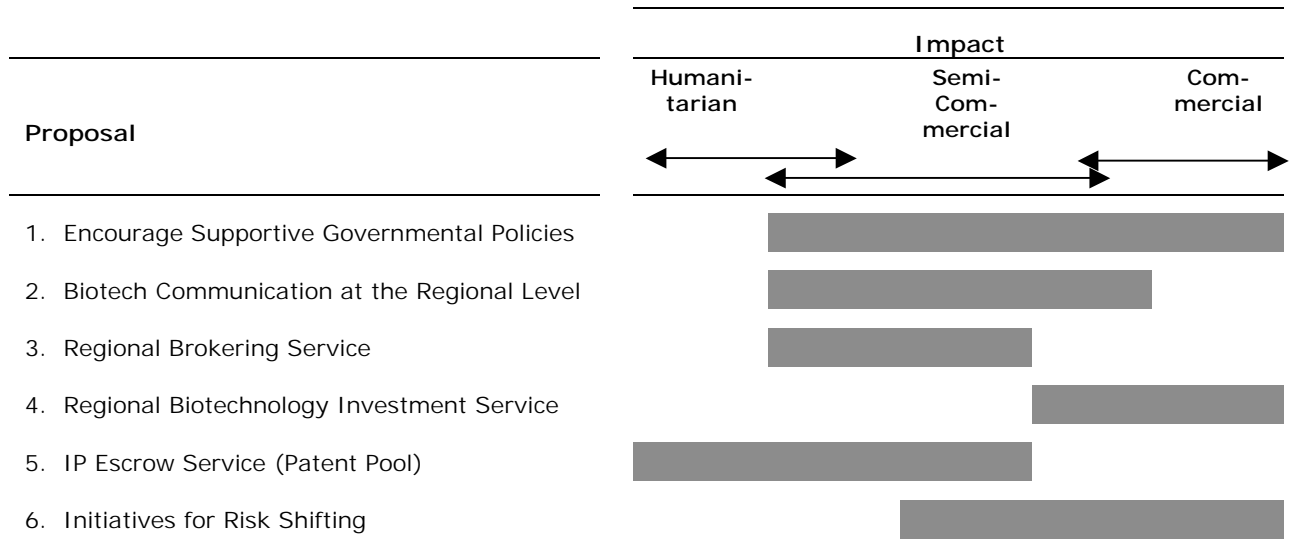
1. Developing and establishing (i.e. institutionalize) **financial instruments to subsidize transactions** (thereby reducing private costs and the potential and scope of loss); to make up losses after the fact; and to spread risk through joint ownership.
2. Developing and establishing (i.e. institutionalize) **liability instruments to provide insurance** in case of mishaps; and to transfer ownership (liability comes with ownership).

Thrust 1 on financial risks is based on the rationale that if the risk/return balance is unfavorable, companies will not enter a market. Such clearly defined risks are relatively easy to compensate for. Mechanisms could include loan guarantees and related instruments. Thrust 2 on liability instruments is based on the rationale that companies are increasingly being held financially accountable for the damage caused by their products. The matter with biotechnology is still very uncertain with the absence of lawsuits to date (the potential acceptable grounds and apportionment of joint liability are still unknown). This is a critical factor that deters companies from participating in biotech transfer activities. Options for consideration here are various forms of insurance, risk pooling methods operating as multi-country pools and shifting ownership.

It is proposed that a consortium be established involving business and law schools at prime universities in Latin America for the concepts to be further developed together with industry, and adapted to national law and customs. This could be followed by high level round tables with policy makers to test/refine the ideas and lobby for their implementation. Note that this proposal directly complements Proposal 4 but the initiative here is aimed at government action (and/or entities such as MERCOSUR).

Conclusions and Options for Follow-up: Given the worldwide emphasis on privatization, there is a mood of minimization for government action. The approach and options proposed here in many ways support that view. Governments are not effective at such things; they are better left to the principals, researchers, inventors, and users at professional institutions. What governments are effective at is broader, longer term activities, those beyond the scope or planning horizon of the direct participants. The proposals suggested here are of that nature. Some could be done by, and perhaps should be done in conjunction with, NGOs. Examples are capacity building and information exchange. Others could be done by private groups with sufficient capital.

The proposed initiatives could also be modified to meet somewhat different needs; much will depend on priorities assigned by the region to the different objectives and constraints. The figure below lists the proposals and demonstrates where their impact would be, based on the proposed strategies. But the mandates of the initiatives could easily be extended or reduced, or shifted in one direction or the other, recognizing that there is considerable overlap in the different areas.



1. Introduction

1.1 *The Advent of Agricultural Biotechnology*

Almost all civilizations underwent a series of technological revolutions; not a phenomenon unique to the Western world. Each of these 'revolutions' involved the application of technology to improve the power of humankind to modify natural systems, ostensibly for the benefit of humanity. In every instance the gains made have been offset by unwanted side effects, including environmental ones. One aspect of that transformation was the invention of the steam engine which marked the beginning of the industrial revolution dating back to the early 18th century. Subsequent economic activity has largely been based on the increased use of coal and other fuels. Only recently are the environmental consequences becoming fully recognized in the forms of global warming and other major environmental changes.

Yet it was only in the late 20th century that it became evident that there is a process of "globalization of technology" underway in which every nation seeks the benefits of technological advances and development, economic growth and improved standards of living for its people. Technology transfer has played in the past, as it will today and in the future, an increasingly important role in enabling different nations to benefit from advances in science and its application in everyday life. Biotechnology is one such advance.

While overall the magnitude of the impact of modern biotechnology on our lives, and on that of future generations, is speculation at best, evidence is fast emerging indicating that the technology will have far reaching impact in every aspect of our lives and spanning across obvious areas such as food and medicine to less evident ones such as electronics and the manufacture of a myriad of items (e.g. airplanes, tires, building materials). Modern biotechnology is often dated to 1973 when the first human gene for insulin production was cloned using recombinant DNA. The beginning of modern agri-biotechnology was in 1983 when the first plant gene was transferred from one species to another. Interestingly, one of the first biotechnology products to receive widespread attention was a number of modified bacteria which were the subject of the patent application by Chakrabarty (1981). The product was developed to assist in the rapid cleanup from oil spills, thus demonstrating the direct relevance of biotechnology to environmental safety. Thus both agricultural and environmental applications are two areas of great expectations for the benefits of people and the environment. Directly, biotechnology will contribute to better nutrition and replace at a far higher degree of safety many of the pesticides and herbicides now in use worldwide. Indirectly, by increasing the productivity of cultivated land, biotechnology can assist conservation by reducing the need for further extensification, often into wilderness areas.

Biotechnology can be classified into two groups, namely traditional and modern. Whereas traditional biotechnology applications have been around for millennia, it is really the modern biotechnology applications that are the groundbreaking applications from a modern technological point of view because of their enormous and hitherto unavailable power to transform living things. Yet the distinction between applications is somewhat in flux, as represented in Table 1 on the next page. What the table illustrates is the different levels of skills, know-how and hardware investments required for applications to become useful. Related to this is the level of intellectual property (IP) protection that can be sought: generally, the more advanced the biotechnology application, the more patentable it becomes. This has tremendous implications in terms of technology transfer and these aspects are discussed in this briefing paper.

This patentability of technology in industrialized countries has spurred significant investments by the private sector. Accurate estimates of global expenditures in biotechnology are difficult to generate and published figures are rarely comparable. Nevertheless they can be used to distinguish orders of magnitude. The most recent estimates by the author suggest that current research and development (R&D) investments by both public and private sector in biotechnology, including medical, agricultural and in-

Table 1: Classification of Biotechnology

	Examples	Skill/Know-How Requirements	Hardware
Traditional uses	Composting, various fermentation processes, vaccines	Low	Very low to sophisticated
Scientific breakthroughs	Cryopreservation, tissue culture, cell culture, plant propagation, DNA analysis, gene mapping	Increasingly sophisticated	Increasingly expensive
Advanced or modern applications	Propagation, genetic engineering, improvement of plants/other organisms, production of enzymes and secondary metabolites, genomics, proteomics	High	High

dustrial, are of the order of US\$ 12 billion annually with approx. 60% of the investments in the USA, nearly 30% in Europe and less than 10% in Japan. Perhaps as little as 20% is invested by the public sector with the majority by the private sector. Of the private investments, almost 80% is invested in medical applications, nearly 25% in agricultural biotechnology (for a total of US\$2.0 to US\$2.5 billion), and the rest in industrial applications. The level of investment into the military and defense area is not known.

Biotechnology investments in developing countries are estimated to be less than 5% of the total investments in global biotechnology R&D. The proportions of public R&D expenditures for traditional agricultural technologies in Latin America, in maize for example (Table 2), represents approximately one third of private investments which is a much higher proportion than for biotechnology R&D.

Opportunities must be created for developing countries to access the new biotechnology applications by building upon private sector investments already made. For geo-political and socio-political reasons—if for no other reasons—such endeavors should particularly be aimed at stimulating economic growth and the reduction of poverty and at contributing to a safer and more productive agriculture. The latter will have an indirect beneficial effect of reversing environmental degradation.

1.2 Objectives of the Briefing Paper

This document will discuss principal elements of technology transfer and highlight the characteristics of biotechnology, and the development of a number of proposals that could be developed into regional initiatives and launched to facilitate and stimulate biotechnology transfer (both in terms of North to South and in terms of local transfers from research to businesses and extension).

As will be made evident from a cursory review of issues related to biotechnology transfer, the emergence of the biotechnology science and technology, while creating major constraints in technology access and transfer, is also creating new opportunities. The South American region is well positioned to meet this challenge. Argentina, for example, at 10 million hectares, had the second highest acreage of transgenic crops in the year 2000 of any country in the world (ISAAA 2000). This represents a 50% increase on the previous year and is equal to one third of the US area planted with transgenics. Also, Uruguay planted 3,000 hectares of herbicide tolerant soybeans in 2000 and Brazil is expected to approve the first transgenic crops later this year. Several countries in the region have high research capacity and, in addition to relatively productive agriculture, offer a good scientific and technological basis for home grown technology adaptation.

Table 2: Investment in Maize Breeding Research in Latin America, mid 1990s
(Source: Morris & López-Pereira, 1999)

	No. of Countries	Maize area (million ha)	Public research (US\$ million)	Private research (US\$ million)	Total research (US\$ million)
Central America & Caribbean	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

Perhaps the major contribution a regional approach can make is at the level of accessing scientific capacity and IP by leveling the playing field for national public and private organizations, thus increasing the efficiency of access to and transfer of biotechnology. The member countries of MERCOSUR in particular are uniquely placed to provide leadership in the developing world in general and in Latin America and the Caribbean in particular. Intellectual leadership is required for developing and implementing a joint response to the challenges posed by biotechnology, and direction in implementing appropriate actions to capitalize on the opportunities. This report initiates the conceptualization process along the lines identified in the objectives below.

Specific objectives of the briefing paper are as follows:

- examine principal elements in technology transfer and distill unique characteristics of biotechnology in terms of technology diffusion;
- identify major constraints hindering biotechnology transfer;
- determine what role the governments in Latin America could assume to facilitate biotechnology transfer, particularly through the Regional Biotechnology Forum and possibly through the yet to be established Latin American Biotechnology Consultative Group;
- determine what role regional institutions could assume to facilitate biotechnology transfer;
- develop alternative roles the private sector might play within the regional framework; and
- specifically explore the contribution of new institutional mechanisms that could provide assistance in accessing proprietary science.

It should be noted that although the overall objectives of the paper are to stimulate thinking and eventually lead to political, policy, administrative and possibly fiscal measures by the governments in the region, the immediate aims of the report are more specific, namely aimed at stimulating discussion during the *Regional Biotechnology Forum—A Latin American Biotechnology Initiative* in Montevideo from 28-30 March 2001, and provide working groups with specific proposal to which they can react to. Certain ideas might outright be rejected, others may be considered too long term, while others perhaps might be explored further in committees after the meeting. But it is hoped that a few ideas will be taken up by the participants and further developed, including an implementation plan and the identification of people who are willing to take the execution of the plans into their own hands.

The proposals for consideration place emphasis on mechanisms that may lend themselves for sub-regional, regional and international collaboration, rather than on more narrow elements for individual national institutions or programs. In particular, the document is intended to identify areas where countries in the regional could capitalize on the presence of a good biotechnological R&D capacity by the

public sector and the advanced stage of commercialization of biotechnology products in certain countries by the private sector. Much of what the governments and regional institutions can do is to support private interests and activities—be they national or transnational companies—thus responding also to the needs and priorities of farmers and the market economies. Other policy choices are discussed, recognizing that governments do not formulate and implement policies in a vacuum. The question for this paper is what initiatives the community present at this conference can do to stimulate public policy formulation to accelerate access to biotechnology applications and diffusion of the products to farmers, ultimately leading to a more productive agriculture. One of the constraints a regional approach will face is the different priority needs of individual countries and the ensuing differences in strategies to pursue the same overall objectives.

2. Technology Transfer and Biotechnology

2.1 *Technology Transfer and Technological Change: Characteristics of Biotechnology*

Any meaningful discussion on technology transfer must first clearly define what “technology” is. Many definitions exist but for the purpose of this paper, the following is adopted: “The phenomena of input quality improvements or an increase in knowledge leading to an increase in output per unit of input...” Hayami (1977). In simple terms this means more output for the same level of inputs, or more product per unit of labor, or more food per unit of land.

Two main applications characterize biotechnology: increased efficiency in breeding crops and increases in the productivity of varieties. Both technological components come in the form of knowledge and material. Knowledge is referred to as “soft” technology while “hard” technology is knowledge in the form of specific products or processes. While technologies typically evolve slowly, large, seemingly discrete changes are referred to as inventions. But while technologies can be nearly anything, technologies are typically problem solving in nature. And because problems are location specific, technologies must be adapted to meet those local conditions. This is a critical point in the development of public acceptance and communication strategies.

Biotechnology, as a technology, has two components: intangible and tangible. The former is “intellectual” in the form of knowledge (e.g. experience, publications, patents about gene sequences), and the latter in the form of tangible materials, also referred to as “technical property” (e.g. actual genes in vectors). This distinction is critical in strategies dealing with intellectual property (IP) and have significant implications in terms of trade in products and in processes of technological change.

Adoption of new technologies (or “technological change”) has permitted the general rise in the standard of living over the past centuries; food production and agricultural development is a case in point. Agricultural production in the late 1990s would, using 1960s technology, require about 45 percent more land. Much of the increased output of course is due to the substitution of other inputs, especially inorganic fertilizers. But the real technological change has been in seed which is estimated to have provided half the increase. That change in the seed is due to two factors, namely increased efficiency in breeding and crops and the deployment of more productive varieties.

Whereas there are several theories of technological change (review by Kinnucan, Molnar and Hatch 1989), the practical conclusions are that the early adopters gain the majority of the economic benefits from technology adoption and technological change. This has already been demonstrated in agricultural biotechnology studies examining the adoption of transgenic insect resistant cotton. Over the first three years of technology adoption, early adopters in the US captured around one third of the added value whereas those who had not yet adopted the technology loose value of their plantings (Falck-Zepeda,

Traxler and Nelson, 1999). The remainder of the added value was captured by the technology inventor, the seed producer, the consumer and the processors (in approximate order of importance).

Because technological change is an area that affects neighboring countries, both economically and environmentally, any strategy related to the acceleration of access to and deployment of new technologies, to be effective, requires regional collaboration and coordination.

For the first entrants, profits are higher with stable prices and more saleable product with no comparable increase in inputs. However, eventually the increased output will cause prices to fall (demand curves are presumed to be downward sloping). This means that non-adopters are suddenly worse off with no change in input costs but lower market prices for their products. For them the choice is to adopt the new lower cost technology or go out of business. The process may be slow or rapid, but the outcome is the same, effective technologies eventually become ubiquitous.

The discussion here in part explains the development and diffusion of new technologies. Related to this aspect is trade which deals with such issues as why technologies are acquired from abroad as opposed to being locally developed. This is particularly relevant with biotechnology since to-date, most scientific advances have come from industrialized countries. Due to a higher concentration of scientists, bigger capital and R&D investments, and perhaps policies such as those related to the protection of IP, mean that certain countries have a certain near term "comparative advantage" in technological investments.

The development of complex technologies tends to be education intense and, depending on the form, equipment or capital intense as well. Given the uncertain nature of the results, technology creation tends to be risky. Taken together, these factors explain why some kinds of technology tend to be produced by larger private companies or by governments of wealthier countries. This is almost invariably the case for new technologies. These two entities have the financial resources to absorb the uncertainty of R&D investments. For countries to have comparative advantage in technology investments, national scientific and technological capacity has to be developed and government policies must be conducive to such developments and investments. This is closely related to economic development.

Biotechnology is knowledge based and hence is a non consumable good. Non consumption goods are those which are not diminished when used by an additional person. Sharing food always involves a reduced amount for the supplier while an idea can be shared with no diminution. The capturable value of the idea may be diminished and is the reason for the use of patents and IP. But the quantity of the idea is not reduced. For these two reasons, biotechnology is ideally suited to be traded and, in a general sense, the importance of biotechnology trade will increase, both in terms of knowledge and of material property.

Biotechnology, however, must be adapted to local conditions, germplasm and environmental needs. Thus trade will most often be in the general form rather than the finished form. Some adaptation is purely technical. But an equally important aspect is cultural. Because biotechnology essentially is "ideas", it is inherently cultural, which both shapes the technology and is shaped by technology. The introduction of biotechnology applications, therefore, requires communication endeavors that relate the technology to local values. This is one particular area where the life sciences companies made significant errors in the late 1990s in Europe where they placed exclusive emphasis on scientific facts and positives images, but failed to link the images with cultural values.

2.2 *Biotechnology Transfer and the Private Sector*

Technology tends to follow set stages and forms. Companies entering international technology markets typically go through a two tiered decision process. First the choice is between exports of goods and production in the target country(ies). Second is the decision of the business form for local production, whether license, joint venture or foreign affiliate. Export decisions are based on a range of criteria, in-

cluding national and recipient country conditions. Decision factors include market knowledge and size, risk, size economies in production, need for local adaptation, and recipient country regulations. Typically, companies prefer to enter new markets with exports before making the longer term, and more risky, commitment to local production.

When exports are not possible or permitted, companies consider alternative forms of local production. Licensing has the benefit of affiliation with established local partners and less investment risk. Disadvantages are limited control over the technology and quality assurance. Joint ventures are often mandated by national law which in many countries, especially developing countries, stipulates majority national ownership. Joint ventures are riskier because they imply a fixed in-country investment. Subsidiary operation is at the same time the source of the greatest control and the riskiest due to the fixed investment.

Associated with these methods of transfer is the forms of transfers. The most immediate is the transfer of products for direct use. These must be products of broad adaptability or larger markets justifying the expense of adaptation in the home operation. Capacity transfer refers to the dissemination of the capability for local production. This would be compatible with joint ventures and direct investment, and with certain forms of licensing. Finally, design capacity refers to training and related investments leading to the ability for local adaptation or further product development. Because design capacity carries the risk of creating a competitor if control is lost, subsidiaries are preferred for this type of transfer.

It is important when discussing technology transfer to remain cognizant of the appropriate form and stage. Many developing countries are interested in design capacity transfer, which, from the recipient country perspective translates into value added. Yet because this is often the most complex and risky activity for the private sector (i.e. the supplier of technology in this case), opportunities will necessarily be more limited.

In terms of donations of biotechnology applications for humanitarian and resource poor farmer use, the same constraints apply in principle. Based on the experience of the author, the four major concerns of companies are:

1. risk of loss of control of the technology;
2. potential negative public relations if the products disseminated do not meet high quality product standards, thus indirectly defaming the technology and/or company;
3. potential negative public relations if regulatory procedures, such as biosafety and food safety, are not followed; and
4. longer term risk of creating or strengthening competitors.

At the same time, the opportunities and rewards for humanitarian transfers are significant (besides the intrinsic humanitarian, ethical and social benefits):

1. delegation of technological leadership;
2. sound regulatory development based on well trained and informed personnel;
3. national technological capacity which is a prerequisite for technology adaptation and long term growth;
4. goodwill and long term relations based on mutual trust and understanding; and
5. improvement of the public image of biotechnology and of the company.

2.3 Biotechnology and the Connection with Biodiversity and Genetic Resources

It is interesting to note that technology transfer can be defined as the geographic movement of productive capacity. Genetic material, therefore, too is a technology, for it is the means of developing a range of new products; it is productive capacity in an unrefined form. One of the distinctions between such "genetic technologies" (a concept proposed by Lesser and Krattiger, 1994; i.e. crop germplasm, biodiversity, wild biota) and "biotechnology" is that the former is loosely defined and constitutes the delivery mechanism for biotechnology applications. Inventions are better defined and patentable and have very different characteristics in terms of trade requirements.

The link between biotechnology and biodiversity/genetic resources has become stronger with modern biotechnology applications, such as bioprospecting, marker assisted breeding, genomics and proteomics. A variety of biotechnological techniques have come together and enabled bioprospecting, particularly from the gene rich developing countries in the tropics and sub-tropics. An event which occurred in 1991 focused attention on this form of use of biodiversity. That event of course is the agreement between Merck and the National Biodiversity Institute of Costa Rica (known by its Spanish acronym INBio) for the payment of collection fees and a subsequent royalty on any commercial products for the opportunity to screen samples from Costa Rica. The search for new compounds based on natural products has led to many pharmaceutical companies entering into alliances or limited partnerships with major research institutions in the early 1990s.

Contrary to early expectations, the number of deals made have been low. This is partly due to the significant advances in alternative technologies, and partly to the tremendous complexities brought about indirectly by the Convention on Biological Diversity (CBD). Initiatives encouraged by the CBD led to changes in national law reinstating the sovereignty of governments to regulate access to their biodiversity. This means that companies need to enter into agreements (this may be in the form of contracts or of material transfer agreements that stipulate "equitable" benefit sharing arrangements) in order to have access to such genetic resources. Yet there can be no definition of equitable (except in the eyes of the beholder). Companies have shied away from many deals because having to cope with the ensuing legal, public relations and other complexities has essentially been too costly compared to the potential return from alternative investments in technology. An other major reason why companies have shed away from such deals is that the development of access, material transfer and licensing agreements has been extremely difficult in many instances. This is not surprising considering that the policy environment evolved and changed rapidly, that no standards have yet been set, and that negotiations were often conducted with inexperienced negotiators. These factors together have made the development of further access agreements a risky endeavor.

In the case of crop genetic resources, transfers of germplasm have long been the backbone of plant breeding which contributed to over half of all agricultural productivity increases over the last century. Contrary to popular belief, transfers over the last few decades have predominantly been South-South. This is largely due to the work of the centers of the Consultative Group on International Agricultural Research (CGIAR) which shares millions of breeders lines every year from many crops. Most of the original genetic resources come from and are shipped to developing countries. This is not to say that industrialized countries have not benefited. In fact, estimates show that agriculture in the US and Australia benefited significantly from the breeding work of the centers with a very high return on investment (based on the two countries financial contributions to the CGAIR system).

Movement of "raw" germplasm from developing country to developing country has limited value unless value is added through local breeding and adaptation. Yet perceptions have often been that countries who agreed to share genetic resources gave valuable materials away for free. This may well be the case but the exchanges have most often been two-way. In the aggregate, every country has significantly benefited from the free exchange of crop genetic resources and it is not clear how the new international regimes being established that hinder genetic resource transfers will impact future increases in agricul-

tural productivity. Unless efficient valuation and exchange mechanisms are developed, the risk will be that the transaction costs will far exceed the value of the added value the germplasm exchange may provide.

2.4 Proprietary Science (IP and TP) and Biotechnology Transfer

The rights that are commonly referred to as Intellectual Property (IP; see also *A Note on Definitions*, page *ix*) include a variety of rights provided by various forms of statutory protection laws: various forms of patents, Plant Variety Protection (PVP), trademarks, copyright, designs, trade secrets and the like. Such rights are instituted and enforced on a country-by-country basis and their scope varies across countries.

Until the mid-1990's, subsistence agriculture greatly benefited from public technologies that emanated from universities (both public and private) and international research centers, such as those of the CGIAR. With the increased globalization of agriculture, however, new "life sciences" companies had been created³ that sought to expand their market share in both developed and developing countries. These companies have made massive investments in biotechnology R&D, and in order to profit from their investments they sought IP rights for their discoveries. At the same time, many developing countries have begun to demand a "fair share" of the value of their country's biota. These factors have moved all the players to try to build IPR "fences" around their discoveries in biotechnology or germplasm.

Biotechnological components have become widely integrated into plant and animal breeding strategies within both the private sector and increasingly within the public sector. But the differences between the private and public sector's approaches to IP issues is slowing the dissemination of these new technologies to those who need it most: the world's resource-poor farmers. At the same time, the proprietary nature of the science is strengthening new alliances such as industry-university partnerships and other public-private partnerships and has enabled a significant increase in venture capital for start-ups. The number of new and small companies focused around a particular invention or platform technology has been rising over the last few years, particularly in the US and Germany.

For many years, developing countries and the institutes assisting them with agricultural research and product development had paid little attention to IP rights issues. But recently, as their international agricultural research centers prepared to deploy products improved through biotechnology, many countries began to better appreciate the need to obtain the appropriate licenses for the components that they had used to develop their products. These countries have realized that there are advantages in participating in IP protection systems, not least because of their obligations under the Trade Related Aspects of Intellectual Property Rights (TRIPS) agreement of the World Trade Organization (WTO). Some feel that without participating in such a system, the risk for being cut off from more advanced biotechnology innovations in the future and threatened by legal action is too high. In addition, many countries are discovering that efficient IP management systems provide them with greater access to proprietary technologies, which facilitates reaching research and product development goals more quickly and less expensively, ultimately benefiting the farmers and national agricultural economies.

For example, at its mid-term meeting in 1998, the CGIAR began to study the impact of IPRs on their research and product development efforts. Some centers had already entered into collaborative re-

³ With the slowdown in the growth of food biotechnology or transgenic products, the life sciences concept was dismantled and almost all former life sciences companies (Novartis, Monsanto, Aventis) re-structured and sold their agricultural units. Novartis' ag business became Syngenta following the merger with AstraZeneca, Monsanto was essentially purchased by Pharmacia Company prior to the partial spin-off, and Aventis announced earlier this year that it was seeking buyer of its Aventis CropSciences unit which had been created following the merger of Hoechst (including AgrEvo) and Rhône-Poulenc.

search agreements, material exchange agreements or licensing agreements with private or public sector entities, such as multinational life sciences companies or universities that possessed advanced IP/TP rights management mechanisms. Many other centers, however, had little experience with such matters. The CGIAR has also begun to consider the full impact of its Food and Agriculture Organization (FAO) of the United Nations germplasm trust agreements and how these agreements impact clients in developing countries and research partners.

One reason the centers took IP management very seriously is because consistent IP policies and professional IP management is a pre-requisite to working with the private sector. Driven by their desire to capture returns on their massive research investments, the private sector has always moved quickly to obtain IP protection for their innovations. Publicly funded researchers, however, until the late 1980s, did not systematically protect their research results. Today, both private and public sector scientists are making greater efforts to protect the IP rights related to their discoveries. This shift appears to have been driven by three synergistic forces:

- the globalization of agriculture (including its research);
- the increased capital required to develop, advance, and exploit biotechnology; and
- the effects of certain international agreements, such as the CBD and TRIPS.

Typically, the private sector seeks to recover its massive biotechnology investments from customers in developed countries. Their business plans also attempt to open new markets to biotechnologically improved products primarily within the more advanced developing countries where certain economies of scale can be achieved. The public sector, on the other hand, is typically required to disseminate the products of research efforts to developing country clients at subsidized prices. These differences, however, actually offer multiple, although sometimes hidden, opportunities for the public and private sectors to reach their respective goals. The challenge is to set mechanisms in place that assist the various parties in recognizing opportunities for mutually beneficial partnerships. And IP/TP rights management is at the center of a plethora of such opportunities. It focuses both the public and the private sector on immediate, effective, profitable as well as humanitarian ways to move forward.

As the private sector seeks to expand its market, it will need a vehicle to bring technological advances to farms in developing countries, particularly those farms that are in transition from a subsistence to a commercial level. At the same time, the public sector needs licensed authorization from the private sector to incorporate the private sector's discoveries into its improved products and related information. Again, IP management is at the nexus that brings the different sectors, public and private, together to reach their respective goals. Since any partnership is based on trust, an important prerequisite for effective public-private partnerships is the mutual respect of each other's property.

A final aspect of IP management is the need to have freedom-to-operate (FTO) for the entirety of the IP and TP rights embedded in a product. This is particularly the case if the products are eventually traded. Otherwise, the public sector—or a private company for that matter—will be unable to deliver its best and most current product improvements to its clients. To accomplish this, appropriate and comprehensive institutional IP management systems are required.

2.5 Lessons from Existing Mechanisms and Institutions in Biotechnology Transfer

There are a host of public organizations providing services related one way or another to biotechnology transfer. These include (in alphabetical order) ABSP, BTG, CAMBIA, CAS, IBS, ICGEB, ISAAA, ISNAR, REDBIO and many more. Although there is some overlap between organizations and the services they offer, each really fulfills a certain function different to others or places more emphasis on certain areas.

This is quite natural and desirable since the needs are tremendous and no single organization can fulfill all needs.

CAMBIA, for example, has a primary goal to develop and adapt biotechnologies for the needs of developing countries. It operates out of Australia and adapts proprietary and non-proprietary technologies for transfer to developing countries. **ISAAA**, on the other hand, places emphasis on brokering transfers between the private sector in the North and the public sector in the south, operating almost exclusively in Africa and Southeast Asia. In Latin America, at least three regional organizations are active in biotechnology transfer, namely **IICA** and **CamBioTech**, the biotech transfer initiative for Latin America and the Caribbean of IDRC, and **REDBIO** of FAO. IICA, in principle, aims at facilitating technology transfer and harmonizing biosafety, phytosanitary and IP approaches in its member countries (all of the western hemisphere) whereas REDBIO acts as an information clearing house for a multitude of needs. In addition, the centers of the **CGIAR** function to a higher or lesser degree as biotechnology transfer organizations. Those headquartered in Latin America, namely CIAT, CIMMYT and CIP are also some of the most advanced ones in their internal biotechnology capacities. Evidently, there are a host of private organizations; listing them alone would exceed the scope of this paper. (Suffice to mention the private law firms and technology brokers, such as the British Technology Group (**BTG**)). The latter conducts technology valuations, builds patent portfolio for its clients free-of-charge, and then markets such portfolios with a corresponding commission. Below is a more detailed account of some of the organization's strategies and activities.

In terms of barriers to biotechnology transfer, the author's personal experience while leading ISAAA was that intellectual property rights, per se, were not the major stumbling blocks, although their resolution demanded a significant effort. The main constraints in the author's opinion were:

- the low absorptive capacity of national programs and weak product dissemination/commercialization systems;
- the often lacking regulatory capacity in developing countries (biosafety, food safety);
- the lack of risk takers in developing countries;
- the strategic interest (or lack thereof) from the side of corporations; and
- the high value corporation's placed on product stewardship.

As mentioned above, technology transfer is not a new activity. What is new is the form of the technology, now often living matter owned largely by private companies. This is a major departure from earlier practices, especially as it applies to agriculture. The case studies below demonstrate that there are a number of parallels of purpose and method among them. The overlaps, however, are an indication of pervasive needs in biotechnology transfer with developing countries. A principal overlap of the cases is in the areas of information and assessment, regulatory assistance, training, and more proactive functions of "honest broker". The fact that there is a demonstrable need for these activities suggests that technology transfer is not self-satisfying through market mechanisms. (Alternatively, our modern information age and changes in the way information moves may simply make us less patient; or, more significantly, the sheer number of people living in poverty constitutes a moral imperative). Among the factors involved is the time span from first development to transfer of the technology to commercial use. The duration eliminates private sector interest for all but the largest markets and product segments. There is a great need for suitable positive actions to serve as an intermediary between users (be they NARS or national private entities) and suppliers of biotechnologies.

The conceptual underpinning of most organizations involved in international agricultural development (as well as actual experiences) indicate that technology does not transfer as goods or products only, but as capacity. Capacity implies human capacity, capacity to assess, to regulate, to absorb, and to modify

as needed. Hence there remains a major training function in association with technology transfer, and governments are the major supporter of training world-wide. Regulatory oversight (biosafety) and IP management systems are but specific examples in technology transfer of needed areas for training. Another, and at present increasingly popular development activity, is policy support. This has become evident through the many workshops as well as information systems that have sprung up in recent years.

What the case studies lead to conclude is that transferring biotechnology to developing countries is a dynamic, unfolding process that requires flexibility, the building of trust between collaborating institutions (public and private), and assistance with the technology transfer process down to final product development and distribution to farmers. Of any of the projects brokered by the institutions mentioned above, few if any have reached the end user as yet. This, however, has to be seen in perspective because plant breeding, testing and seed multiplication is a long-term process. All institutions analyzed also have a significant capacity building component which is aimed at building sustainability into the biotechnology transfer process besides regulatory capacity development and an impact on positive public perception. With most projects, it is hoped that the partnerships thus developed will lead to future projects independently developed by participating institutions.

Whereas some of the institutions will have a positive effect on biotechnology transfer for the non-commercial humanitarian needs, few have addressed the intermediary or semi-commercial markets, namely those that lie outside the potential markets of the larger companies (e.g. soybeans in Argentina and Brazil) and outside the purely non-profit institutions (e.g. CGAIR mandated areas). This is an important sector in Latin America. Most of the proposed initiatives under Section 5 of this briefing paper address precisely that void.

3. Constraints in Biotechnology Transfer and Adoption

3.1 Introduction

One of the indirect stipulations and conclusions of the preceding section was that the general incentive structure favors the international transfer of technologies. Hence, one explanation for an inadequate flow of biotechnology would be (artificial) impediments. This section reviews factors which enhance biotechnology transfer and adoption, and then focuses directly on institutional aspects and impediments of biotechnology transfer.

Technology transfer from developed to developing countries and *vice versa* has been taking place for a very long time. There are many factors that have promoted such transfer, including war, trade, and exploration. None of this is new. What is new is the extent to which the transferring parties are claiming rights in what is being transferred. Previously, transferred objects tended to be tangible things like jewels, land or slaves. Occasionally certain types of seeds or plants were also transferred (for example, coffee from North Africa and rice from Asia to South America, "Irish" potatoes from the Andean Highlands initially to Europe, sweet potatoes and tobacco from the Western Hemisphere to the rest of the world). But in these cases the transferred technologies were what they appeared to be: the objects themselves. They seldom contained embedded "secrets" although they contained in themselves selective breeding and conservation work undertaken by generations of local farmers. However, more recently various types of war booty (for example, medicinal plants together with shamanic knowledge, AGFA photographic film, Germany's secrets of rocketry and the A-bomb) began to include not only the objects that were transferred but also certain "hidden" information as well.

The rights to such embedded information are now broadly being called "Intellectual Property" or IP. Interest in IP rights and an expansion of interest in protecting them has grown significantly during the last 5–15 years. This has been due, in part, to the ease of replication or duplication of certain of the prod-

ucts and with such duplication the “pirating” of the embedded secrets, once one of the “new” items were transferred. Common examples of this would be recorded music, software, or microchip designs. Even such things as Rolex watches and Levis jeans were often copied. The same has been true of statutorily protected plants, plant parts, and seeds.

As the costs and potential rewards of aggressive research, product development, and brand promotion increased, there has been a corresponding desire on the part of inventors and marketers to protect their products from unauthorized duplication. The most obvious path for such protection has been an expansion of statutory protection rights and a more vigorous enforcement of those rights. This has been particularly true within food biotech applications.

For agricultural products, particularly for those containing biotech components, the augmentation of IP rights has been driven by two factors:

- an increasingly high capital investment required to produce successful agri-biotech products and the related need to recover such massive investments plus a profit; and,
- the inability, absent the use of law, of a transferring party to prevent wide-scale pirating of the transferred product once that product has left its control.

Because of the high capital investments needed to develop agri-biotech products, the vast majority of new discoveries and cutting-edge products involve technological components owned by private companies and a few major public research organizations. This concentration of advanced technology has set the focus of corporate marketing, which typically—and for understandable commercial reasons—does not include addressing the needs of the resource poor farmer in developing countries.

Various organizations have seen this need and have attempted to respond to the needs of developing countries. Such organizations evidently include first and foremost the National Agricultural Research Systems (NARS); the independent broker services offered by ISAAA; the project-specific, bilateral United States Agency for International Development’s (USAID) Agricultural Biotechnology Support Program (ABSP) coordinated by Michigan State University; many of the CGIAR’s institutes; the technology-oriented CAMBIA in Australia (Center for Agricultural and Molecular Biotechnology in International Agriculture); the policy-oriented Intermediary Biotechnology Service (IBS) of the International Service for National Agricultural Research (ISNAR); the International Center for Genetic Engineering and Biotechnology (ICGEB) of the United Nations Industrial Development Organization (UNIDO); and many more.

These organizations and programs were all set up at different times to either respond to specific constraints or geographic regions. The broad underlying reasons for slow biotechnology transfer to developing countries can be summarized as follows:

- perceived lack of value, or lack of recognition thereof, of the agri-biotech material to the leadership of many developing countries;
- unpredictable institutional characteristics (such as laws regarding statutory protection and the court systems that enforce these laws, weak or absent biosafety regulatory mechanisms) that govern IP protection and enforcement of IP rights within many developing countries; and
- lack of scientific resources and personnel, and weak or absent institutions required to effectively utilize agri-biotech once it is transferred.

In general, although expanding international trade has increased the transfer of biotechnology, there has been a parallel push to expand statutory protection laws and enforcement within developing countries. The technology owners who have made huge investments in their technologies are reluctant to lose their R&D investment within developing countries. Therefore, they generally limit the amount of

cutting-edge products they will transfer in the normal stream of business. To build a more favorable climate for international trade, many Northern and Southern countries have signed various international agreements (GATT, TRIPs, CBD) that build increasingly high barriers to protect the latest technology. However, coupled with such treaties is an instantaneous need for knowledgeable, experienced personnel to enforce the countrywide laws that are part of such treaties.

Finally, the protection of agri-biotechnology is very costly. It requires personnel and facilities as well as a means of enforcement of statutory protection laws. All of these factors mitigate against the rapid deployment of the newest technologies into the developing world.

3.2 General Factors Encouraging/Discouraging Biotech Transfer and Adoption

New technologies are preferred to old ones because of their relative advantage. Preferences, overall, depend on sociological as well as economic factors, such as:

- Compatibility:** the extent to which a new innovation is consistent with the existing norms, values, and prior experiences of potential users. Also to be considered is the degree of physical and managerial compatibility with existing practices.
- Complexity:** the extent to which new techniques and their consequences are difficult to understand. In general, less complex ideas are more widely and universally utilized.
- Divisibility:** the extent to which innovations can be used on a limited basis. If small-scale trials are possible, the risks are much less than for an all or nothing commitment.
- Communicability:** the relative ease with which knowledge of an innovation can be passed along. Communicability also involves the rapidity and tangibility of the benefits.

Biotechnology applications, considered as a group, fall about midway in the four aspects outlined above. Biotechnologies are relatively complex, and when the release of living organisms is involved, the biosafety aspect is a significant technical effort. Biotechnology applications, additionally, do not always fit within the values of individuals and groups. On the other hand, biotechnologies can be highly divisible—within agriculture as little as a single plant—and may reduce rather than increase management requirements, as with some disease management practices such as Integrated Pest Management (IPM). Biotechnology applications tend to have rather immediate and tangible outcomes.

From a governmental/policy perspective, most of these factors are external (meaning that these factors per se do not lend themselves for government intervention). But several can be affected, thereby indirectly influencing adoption. Certainly the communicability of technology attributes can be affected by government action. Additional attention can be directed to making innovations compatible with developing country users. This is a critical area for assistance by the public sector.

Risk is a recurring theme with new technologies. While a number of risk-shifting approaches exist, such as the supplier retaining ownership and operating on a piecemeal basis with users, most are beyond the control of governments.

Where governments can contribute is divisibility. At one level, divisibility is a company-level reflection of the localness of technologies. Each adopter wishes to know how an innovation will perform in his/her operation; nothing else really matters. Divisibility allows such a small-scale test. When that is not technically feasible, governments can assist with localized demonstrations that allow potential users to examine the effects under very specific conditions. This is one principal reason why the project based

strategies of biotechnology transfer adopted by many organizations (e.g. ABSP and ISAAA) is critical in opening the markets for both the private sector and the national programs alike.

3.3 Specific Constraints in Biotechnology Transfer and Adoption

When considering factors that discourage the transfer of biotechnology applications, at least five main areas can be discussed. Many are directly or indirectly related to IP. These are not necessarily in order of importance, for that varies according to the technology to be transferred and the countries and donors/recipients involved.

3.3.1 Public Acceptance

Biotechnology is currently caught in a maelstrom of controversy; more of it flowing from emotions and beliefs than from rationality. In practice, however, there is much stated opposition to the use of biotechnology in the food supply chain within industrialized countries. Increasingly, many developing countries, fearful of being used as “technology proving laboratories,” have reversed their initial broad acceptance of food biotechnology as the dawn of a new day of food security. Others are shying away for fear of jeopardizing their exports.

Sometimes, the forces opposed to food biotechnology have pointed to the consolidation of the biotechnology industry in the portfolios of a few wealthy entities (multi-national companies, well-endowed universities, etc.) as “proof” that biotechnology is part of a plot to manage the world’s food supply. These anti-transgenic voices point to expanded statutory or IP protection to proof their hypothesis or world views.

Evidently, what happens in Europe in terms of public acceptance will have a world-wide impact, not least because of trade considerations. In the view of the author, it will be another 3-4 years or so before Europeans will more broadly accept food biotechnology.

3.3.2 Technology Cost (R&D)

The capital investments required for successful (or even unsuccessful) R&D in biotechnology are astounding. During the late 1980s, investment banks, private investors, companies, and research organizations pumped very large amounts of capital into biotechnology research and product development. Few of these investments returned the investment and fewer yet produced a profit to the venture capitalists. In an attempt to seek a fair return on their investments, the research entities aggressively pursued statutory protection wherever possible. This aggressive, market-oriented stance within the culture of biotechnology in general, in turn, added additional costs to the R&D efforts. In many cases, it was cheaper and more effective to “buy” entire companies rather than endeavor in lengthy negotiation processes with uncertain outcomes. This may well have been the case for the purchase of Mogen by then Zeneca, or for the purchase of Agracetus by Monsanto.

By the early 1990s, purchases of companies with strong patent portfolios or platform technologies were no longer major options because their numbers had shrunk significantly, either through the purchase or through bankruptcy. The strategy had therefore to be modified and led to the life sciences concept with the familiar mega-mergers. The value of the top 25 consolidations from 1995 to 1998 totaled US\$17 billion (James and Krattiger, 1999). By the late-1990s, a new strategy in technology licensing was pursued with the advent of genomics. Because this was (and still is) a high risk research effort, companies spread their risks by making significant investment deals into emerging genomics companies (e.g Maxi-

gen) or by research collaboration deals and technology licensing agreements with upfront and milestone payments.

In sum, companies have had to consolidate, in part, because of:

- spiraling R&D costs (including regulatory costs and delays);
- high patenting, legal, licensing and litigation costs;
- the emergence of high risk new technologies such as genomics; and
- slow consumer acceptance.

It should be noted that for large companies, failure to be “in the technology game” could have cost them their comparative advantage later on; hence many of the investments were merely viewed as insurance policies. Also noteworthy is that mergers of equals saved those companies much of the patenting, legal, licensing and litigation costs. For example, Novartis may have spent US\$70-90 million per year in the agricultural biotechnology area and AstraZeneca some US\$50 million or more. The combined company Syngenta is unlikely to have a budget of more than 60% of the combined expenditures, or US\$70 million or so. It is perhaps worth mentioning here that the entire budget of the CGIAR for biotechnology is less than a quarter or so of what one major agricultural company spends in IP management! Similarly, the entire budget of the CGIAR is less than what a Monsanto spends in R&D every year!

3.3.3 R&D and Regulatory Capacity

Across the world, from a perspective of agricultural R&D in general, there are three broad classifications that can be readily made. These are:

Type I Highly developed biotech research and regulatory capacity within universities, companies, and public or private research institutions; these have predictable laws, regulations, and enforcement of statutory protection and biosafety regulations. Examples: The European Community, Japan, the United States.

Type II Early stage biotech research and regulatory capacities primarily within parastatal and international research centers and a limited number of universities; recently enacted and unpredictably enforced laws and regulations regarding statutory protection of discoveries and biosafety. Examples: Brazil, India, South Africa, Mexico, China.

Type III Very little or no biotech research and regulatory capacity; have historically depended quite heavily on improved agricultural seed products from the international research centers; very newly enacted statutory and biosafety legislation and no predictable experience in enforcement. Examples: Kenya, Syria, most of Eastern Europe, Vietnam, Columbia.

The international research centers have directed their activities primarily toward serving the Type III and to some extent Type II countries, while their funding sources have been primarily located in the Type I countries. Until recently, research at the CGIAR Centers proceeded without significant consideration of the issues of IP. However, as these Centers prepared to release their first biotech-based improved seed products, there was a realization that few of the IP issues had been adequately addressed.

The impact upon the Centers’ research capabilities because of a failure to resolve the IP issues for their improved products is only one aspect of the problem. The more critical one is the limited ability of the centers of the CGIAR’s client countries, whether Type II or Type III, to receive and manage the Centers’

improved products. This has placed a significant hurdle in front of the effective distribution of a great deal of very expensive research that has been done by the centers.

The high costs associated with delays in field testing and fully developing adapted products for poor farmer or commercial farmer use is at least in part due to the lack of regulatory capacity. Whereas many initiatives had begun in the early 1990s to build capacity in developing countries in this area, few have established functioning and effective biosafety mechanisms. Many countries have been waiting for the deliberations at the CBD to come to closure with the Biosafety Protocol. Yet what seems to have been forgotten is that biosafety still needs to be dealt with on a local/national level and that capacity must be put in place irrespective of whether or not a Biosafety Protocol exists. Much valuable time has thus been wasted with no apparent benefits.

3.3.4 Seed Distribution Systems

Most agricultural products, because they are living organisms, have the ability to reproduce themselves. With the inclusion of transgenic components in many recently released improved agricultural products, they pass along their biotech components, whether the components are IP-protected or not, from generation to generation. Biotechnology has thus prompted the invention of new seed marketing schemes and is calling into question the historical patterns of seed distribution. Nowhere is this shift expected to be more dramatic than among the Type II and Type III countries. The expensive proprietary technologies, it is feared in many quarters, will become public property in many such countries.

At the same time, the Type II and Type III countries are the ones that could potentially most benefit the most from the technological advancements that are protected by IP, both from a socio-economic and environmental perspective. This conflict has promoted the development of "locking" technologies such as the so called "terminator gene". This "locking" gene had great potential to minimize the risk of environmental harm by transgenic crops while permitting the owners of IP protected components to extract a return on their investments. Whereas for public relations reasons the "terminator" will not be developed and incorporated into seed, other gene regulation technologies are likely to become the dominant mechanism. They are expected to emerge within five or so years and afford acceptable IP protection in many crops, markets and circumstances.

Until more predictable IP laws and enforcement mechanisms are in place in many developing countries, it appears that many of the benefits of the food biotechnology applications will be denied to resource-poor farmers. New systems of improved seed and agricultural product distribution may be required that allow the developing country farmers to benefit while not denying a proper return on their investments by companies.

3.3.5 IP Complexity and Freedom-to-Operate (FTO)

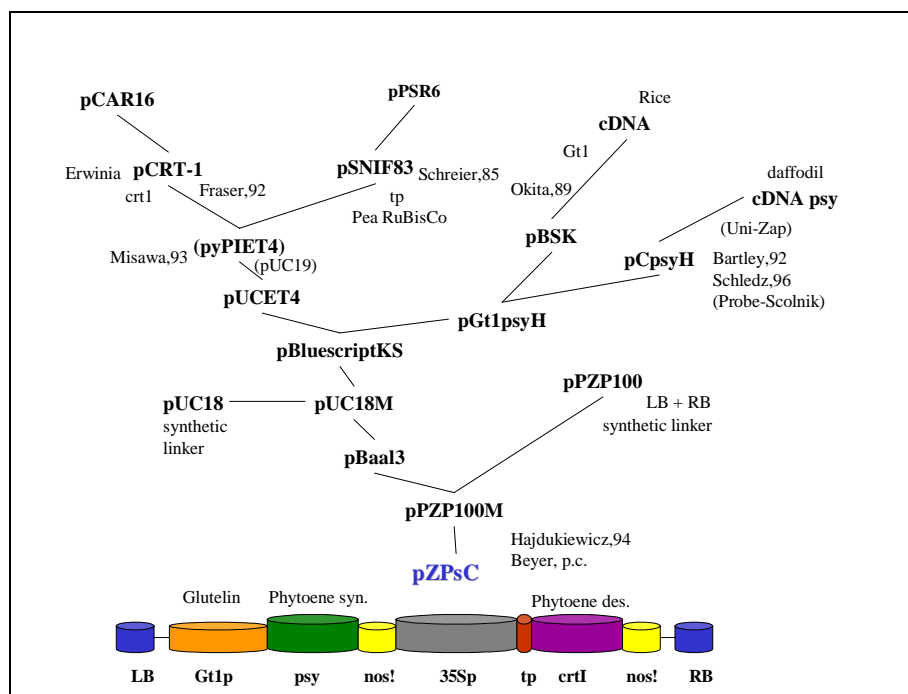
In addition to the complexities that are inherent to statutory protection laws worldwide, the impact of various international treaties (GATT, CBD, TRIPs, etc.) has added another level of complexity. Further, as developing countries modify their legal systems and practices in response to the various laws and treaties, an even wider range of complexities begin to arise. The factors that discourage widespread adoption and easy transfer of agri-biotechnology are many and diverse. However, they are principally related to IP management activities.

A recent FTO review of the pro-Vitamin A containing Golden Rice has shown that a total of about 70 patents are embedded in the product. Because patents are granted on a national basis, in a given coun-

try fewer than the 70 patents apply and range from zero in some developing countries to as many as 45 in most of Europe and the US (Kryder, Kowalski and Krattiger, 2000)⁴.

Determining what entity has the right to grant licenses or sub-licenses is a very tedious process, one which continually evolves as companies re-structure, sell or assign patents, or grant licenses with or without the right to sub-license. The technical property (TP) flow further complicates the picture as is evident from Figure 1 which lists the TP flows for one of the three constructs necessary for the production of Golden Rice. In addition, “recognizing that patent claims may be granted for different kinds of inventions, claims may be worded to cover products *per se*, products-by- process, uses, or processes. Whereas the first three types of claims generally extend to the products that embed the new discoveries, “process” claims or claims for the claimed technical procedures do not extend to the products that are produced by the claimed processes. What is of great importance for “process” claims is the country in which the process is applied. If the product is made in a country where those “process” claims have not been issued, then a license for such claimed processes are not required” (Kryder, Kowalski and Krattiger, 2000). A total of 26 of the approximately 70 patents identified in the above study contain primarily process claims thus reducing somewhat the number of applicable patents which could inhibit FTO in a given country. A detailed analysis on a country-by-country basis may reduce the complexity of the IP landscape.

Figure 1: Flow chart of Tangible Property Transfers for one of the three constructs of Golden Rice (source: Kryder, Kowalski and Krattiger, 2000)



⁴ In the USA and most countries of the European Union, around 40 patents apply. In the 10 top rice producing countries, many fewer patents apply, namely: China (11), India (5), Indonesia (6), Bangladesh (0), Vietnam (9), Thailand (0), Myanmar (0), Japan (21), the Philippines (1) and Brazil (10). Similarly, in the top ten rice importing countries, relatively few patents apply: Iran (0), Brazil (10), Nigeria (0), the Philippines (1), Iraq (0), Saudi Arabia (0), Malaysia (0), South Africa (5), Japan (21) and Côte d'Ivoire (10).

3.4 Government Policy Choices

The implicit perception that biotechnology transfer is not self-sustaining through market mechanisms is indeed correct. Among the factors involved is the time span from first development to transfer of the technology to commercial use. The duration eliminates the private sectors interest for all but the largest markets and product segments Paarlberg (2000) recently analyzed the policies towards agricultural biotechnology of several developing countries and concluded that the difference between the most restrictive and liberal countries essentially lied in five policy areas:

- **Intellectual property rights:** granting patents on plants (as is possible in the US) encourages adoption of transgenic crops. Intermediary policies are adherence to the UPOV convention and the granting of Plant Breeder's Rights.
- **Biosafety:** blanket approvals for certain technologies or crops encourages adoption whereas a case-by-case approach is more restrictive.
- **Food safety and consumer choice:** In this area a promotional policy would be to conclude that transgenic crops currently on the market pose no new hazards to human health and to impose no additional inspection or labeling burdens on them.⁵
- **Trade:** a promotional trade policy to ward transgenic crops would be to seek the import of transgenic plant materials and seeds without restriction and promote the planting of transgenic crops in hopes of cutting farm production costs and becoming a more competitive exporter.
- **Public research investments:** Developing countries must also make a range of agricultural research investment choices toward transgenic crops. At one extreme they might spend treasury resources to develop their own transgenic crops. As a second option they could invest only in the more limited goal of backcrossing transgenic traits developed by others into their own domestic germplasm. As a still more limited option they could allow their scientists to pursue backcrossing of transgenes into local varieties, only if donors were willing to pay for it.

Whereas the first three aspects are undoubtedly encouraging or discouraging adoption of transgenic crops, the latter two are more in the gray area. For example, the public sector in a given country does not necessarily need to invest significant public funds into the development of products. In fact, this may make it a competitor to potential private investors with the result of reducing the overall speed of adoption of transgenic crops. Investments in national research and science capacity is a different matter since trained personnel and experts in this technology are required for government policy advice and regulatory development in the short term and for the fomentation of national business ventures in the medium term. Another, and at present increasingly critical development activity, is international policy support. Countries passing through the transformation to more open economies, or of implementing TRIPS requirements, have to change many policies and procedures. Indeed, the openness to accessing agricultural biotechnologies under many new international treaties (particularly the CBD) is an example. What is certain is that governments must make choices and stronger IP protection, efficient biosafety approval mechanisms, proactive food safety and public acceptance policy, liberal trade and appropriate public investments in national research will favor the adoption of transgenic crops.

But governments do not formulate and implement policies in a vacuum; complex socio-political forces come into play. The question for this paper is what initiatives the community present at this conference

⁵ Note, however, that the absence of labeling does not provide consumer choice. This is an area where the author of this Briefings Paper begs to strongly disagree with Rob Paarlberg. Whereas food safety and the absence of labeling may be viewed as proactive policies, the experience in Europe certainly suggests that if labeling had been introduced from the outset (as indeed they originally had when Zeneca introduced its clearly labeled transgenic tomato paste in 1994), transgenic foods would have been accepted. Finally, "food safety" and "labeling" are not matters which are related *per se*; "labeling" and "consumer choice" are related.

can do to stimulate public policy formulation to accelerate access to biotechnology applications and diffusion of the products to farmers, ultimately leading to more productive agriculture. A number of more proactive initiatives are proposed in the section below, which are critical to biotechnology transfer, and lie outside the purview of governments. One of the sources of high costs, and hence risk of loss, is the "learning curve" for new technology market development. Indeed, a critical role of broker services is the pioneering of new long-term markets, even on behalf of large companies. As will be discussed further down in this paper, ISAAA is a case in point which has indirectly been performing some of the market entry functions, assisting national and multinational companies as they enter those markets. This requires specialization in biotechnologies and regions, and now in specific areas that impede the transfer of biotechnology.

The NARS seeks a technology that is proved (or soon provable) to solve the agri-problem that is presented. As such, it must be within the range of expertise of the NARS staff or the staff must be capacitated to properly manipulate and manage the new technology. Likewise, the NARS is concerned about safety; both biosafety and food safety, as these apply. Finally, from a scientific perspective, the NARS is concerned that implementation of the new technology does not precipitate other problems. From the perspective of IP management, for example, the NARS are concerned that the technology it is receiving has FTO within the recipient's country. In some cases, the NARS may seek a proviso to assure that it can obtain the appropriate licenses required to export its technologically improved products to one or several countries. Tied with such licensing arrangements is a NARS need for adequate skills, tools and personnel to manage the IP/TP issues of the brokered agreement.

Yet the NARS does not receive the transferred technology for itself; it is a conduit for the technology to the resource-poor farmer/consumer. So, the needs of that farmer (and the ultimate consumer, if the farmer sells some of her/his produce) must also be considered. Here, the issue is a cost/benefit ratio that balances the existing, pre-biotech, agricultural practice against the proposed biotech application. While much could be (and has been) said about the economic sophistication of illiterate resource-poor farmers, as a class they are among the world's most savvy business people. They will readily adopt a technologically improved agri-product when they see that the new is better than the old. A corollary to this is that if a technology is NOT accepted, there is a valid need that the new technology is not adequately addressing.

3.5 Institutional IP Management Options

The purpose of this subsection is to describe the IP management options primarily of public entities. Note that whereas the options for public and private entities may be the same, the feasible and effective choices will be significantly different. Public entities will undoubtedly follow closely the strategic choices that companies have to make as part of their R&D planning. The choices made vary significantly for reasons related to R&D capacity, critical mass, cost, legal aspects, strategic objectives, public opinion, etc. The typical difference between a public and a private entity is that the private entity needs to share in the benefits with farmers, distributors and share holders, but both must provide superior products in order to survive. Evidently, the way products are disseminated by the two entities will vary also. Hence the IP management options and strategies of most private entities will be different to those of public entities.

Table 3 describes the ranges of strategic options available to any type of entity, public or private. The options tackle the FTO issue from different perspectives and are discussed in the sub-sections below on the basis of the pro-Vitamin A rice, or Golden Rice. The options range from ignoring all IP to inventing around patents to seeking full FTO through negotiation and more. It is concluded that a mix of approaches is the only feasible and practical one.

Table 3: IP Management Strategies to Obtaining Freedom-to-Operate
(modified after Kryder, Kowalski and Krattiger, 2000)

Title	Emphasis	Description	Pros	Cons
1. Invent around current patents	Science and research based approach	Research alternative ways, generate new discoveries and/or inventions	- Less reliance on patents owned by others	- Time consuming - Costly research - May not be feasible
2. Re-design constructs	Product development based approach	Re-design each construct to reduce number of applicable patents, whenever possible synthesize own genes to reduce reliance on technical property of others	- Normally re-design is necessary after successful research demonstration - Effective way to reduce IP issues	- May require a few additional years for product to be developed
3. IP/TP Owners to Relinquish Claims	Humanitarian approach focused on public perception	All FTO issues for all related activities, commercial or otherwise, are eliminated through public (or private) statements and related activities by the certified owners/assignees of each set of IP/TP rights for making, having made, using, having used, importing, exporting, selling, and having sold all plants, plant parts, and all related products and processes.	- Greatly simplifies licensing negotiations	- A royalty-free license may still need to be negotiated, not least for liability/indemnity reasons
4. Ignore all IP and TP	Short term perspective	All FTO issues for all activities, commercial or otherwise, are ignored, and research and product development as well as plans for general distribution proceed.	- Lowest cost in the short term	- Once product deployed lawsuits may ensue - Potential future delay of product distribution - Difficult relations with IP owners
5. Seek Licenses for all IP and TP	Licensing approach	All FTO issues are resolved by the process of any party (individually or through consortia) acquiring an appropriate (commercial or other) license from the certified owners/assignees for each set of IP and TP rights that are of interest to the licensee. This license may be commercial in nature (a grant to make, have made, use, have used, import, export, sell, or have sold all plants and plant parts and all related products and processes) or a more restrictive one as the licensee and licensor mutually determine to be required.	- Safest route - Ensures good relations with IP holders for future development of products	- Complex - Time consuming
6. Mix of Options 2 to 5	Pragmatic, realistic	Option 2, 3, 4 and 5.	- Effective route - Takes advantage of all available options - Ensures good relations with IP holders for future development of products	- Relatively complex - Relatively time consuming

Evidently, a company will favor options 1, 2 and 5, a public sector entity may not have the resources and pockets to afford option 1 or 2. Yet the public sector may, if FTO information were available prior to the research planning, optimize the product, slightly re-design constructs. The public sector may also for humanitarian reasons, encourage companies to rescind certain rights (OPTION 3); this “moral high ground” is used to leverage additional rights holders to either rescind their claims (OPTION 3) or to reduce their demands within the context of license negotiations (OPTION 5). In the end all remaining unrescinded IP/TP rights can be either licensed (OPTION 5) or ignored (OPTION 4). Such a strategy capitalizes on the upsides of most of the other options while reducing the risks of future complications.

4. Criteria and Priorities for New Biotechnology Transfer Support Activities

4.1 Introduction

The preceding sections can be summarized by stating that conceptually at least, biotechnology has the potential to flow relatively freely around the globe, all the more as it is non-consumable knowledge, subject to adaptation to local needs and conditions. This is especially the case with agricultural biotechnology where knowledge needs to be “incorporated” into crops to be useful, either in the form of breeding practices (e.g. marker assisted breeding, tissue culture) or in the form of novel gene sequences (i.e. genes).

In practice, trade of knowledge and material form is subject to multiple impediments. Governments protect domestic companies from international competition and companies protect themselves as well. Similarly, imbalances in knowledge create risks in the transfer of technology as do differences in views on technology, needs and expectations; all these factors contribute to limiting technology trade flows.

The rapid growth of multinational companies is partly due to the corporate desire to overcome many of those impediments. A new wave of globalization has begun whereby companies increasingly diversify geographically and according to product to reduce cyclical risks. In fact, they operate increasingly simultaneously as inter and intra-national companies to bypass many trade barriers, and with representation in multiple markets they produce and share internally considerable information regarding markets and products. This is nothing but a new form of corporate technology transfer.

Many countries in Latin America are well endowed, overall, with a relatively strong agricultural sector. Some of the strongest NARS are in Latin America and the presence of national and multinational seed businesses add to the productivity. In addition, international trade and regional trade is constantly advancing and being liberalized. This has brought many opportunities for agricultural growth but also hardship on the farm sector which has had difficulties in some areas adapting fast enough to the changing circumstances. From a private sector perspective, growth in the seed market is not expected to be significant in Latin America (only Asia is seen to be a major growth opportunity). What is considerable, however, is the potential value added by products enabled with biotechnology. As a consequence, many donor institutions have felt that the transfer of biotechnologies to the region can be left to the private sector and the relatively strong NARS to meet non-commercial needs.

This is not satisfactory and current private investments in the agricultural sector show that the corporate sector alone does not meet the needs of the range of farmers and farming conditions on the continent, particularly not in some of the staple crops which are so critical for millions of farmers and farming communities. The reason of course has not to do with the potential of agricultural biotechnology, but with the constraints and risks. The private sector in general does not see sufficient near term profit opportunities to justify significant investments in the transfer of biotechnologies to Latin America, save for specific technologies and crops already developed and commercialized elsewhere (e.g. herbicide tolerance and insect resistance in maize and soybeans, insect resistance in cotton).

4.2 Overarching Criteria

The preceding section showed that increased biotechnology transfer to spur agricultural economic development in the short and medium term will require new initiatives and specific actions. In short, what the private sector does not do by itself becomes in part a public responsibility. Similarly, what the private sector cannot do by itself becomes an opportunity for public policy. The involvement of the public sector in technology transfer is fully consistent with its mandate, especially in regards to the general reduction of transaction costs which is non-economical on a company-by-company basis.

Evidently, countries have to set their primary goals and make complex choices on strategies to meet their preferred objectives; each choice leads to different consequences and results. Conceptually, a country essentially may pursue any of the following goals:

- leave the matter exclusively to the private sector; or
- strengthen national public R&D capacity; or
- place priority on an enabling environment encouraging private investments, either direct or through public/private partnerships.

In practice, of course, a combination of the above three policies or strategies will always be pursued. These are most effective if the strategies are adapted to different “markets”. Byerlee and Fischer (2001) discuss market segmentation approaches and one of their conclusions is that biotechnology transfer is encouraged if appropriate market segmentations are pursued (Table 4).

What these approaches simultaneously allow are:

- the strengthening of national R&D capacity (which is critical for capacity in policy formulation and regulatory oversight);
- the near term delivery of improved products to the sector of the agricultural economy which is least included in the seed and technology market (i.e. the poorer farmers and regions which are the primary mandate of the NARS); and

Table 4: Examples of Different Types of Market Segmentation
(Byerlee and Fischer, 2001)

Segmentation Criteria	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 transferred 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 Plantech 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).

- reduce the overall risk of technology transfer, thus increase private investment and participation in the medium term.

What is essential under any strategy is to ensure that new initiatives complement comparative advantages of the different public and private players. This is the inherent approach with public private partnerships: build on the comparative advantage of public and private, North and South, proprietary and public, etc.

Despite the long recognition that returns on agricultural investments are tremendous from a national economic and social perspective, R&D investments in NARS in developing countries have long been a fraction of what industrialized countries invest (as a percentage of agricultural GNP). This is unlikely to change. Similarly, agricultural investments by donor agencies (philanthropic, bilateral aid multilateral funds) have decreased over the last decade and this trend too is unlikely to be reversed. Priorities must therefore carefully be selected if realistic and practical initiatives are to succeed. Emphasis, therefore, is placed on how to complement what existing institutions and mechanisms are already doing.

Overall, it is recognized that more centralized activities and close cooperation among countries are the most effective ones, precisely because biotechnology is such a potentially highly tradable technology. Cooperation can be limited to sharing information, or go as far as pooling certain skills, patents and activities. For example, management of IP has high costs and whereas each individual institution must have a certain level of internal capacity, none can be expected to develop the critical mass necessary to perform all the necessary functions. This, however, does not apply to the multinational private sector without reservations. As stated earlier, the extensive consolidation in the 1990s within the private sector through takeovers, mergers, and alliances has resulted in an unprecedented concentration of agri-biotechnology R&D resources in five major multinational companies. This situation has given the multinational private sector a number of comparative advantages: a critical mass of R&D resources for funding long-term and speculative projects; economies of scale in relation to global markets; development costs that can be amortized over the long term; and expertise in marketing and distribution of seed

In sum, the main criteria for the subsequent proposals are:

- build on comparative advantage;
- adopt different technology transfer strategies to segment markets; and
- facilitate public-private partnerships.

Many proposal deal with the leveraging of new investments, in terms of when, in what form and with what criteria. In general, it is proposed that investments should neither supplant the private sector nor should they act as indirect subsidies. Rather, any new monies must serve to attract additional private sector investments by making private sector investments less risky and more profitable. That is, the proposals are focused on identifying and overcoming "market failures" through the skilled placement of investment funds.

4.3 *Layout of the Proposed Options*

The proposals do not focus on any potential research agenda. The organization and funding of international agricultural research and of NARS have been reviewed extensively (see Anderson 1994, still one of the most relevant studies) where the legal, regulatory and institutional limitations to agricultural, environmental and health problems were analyzed. That study concluded that technological solutions may

be the most effective in many cases and proposed a much broadened agricultural research agenda for the CGIAR and for NARS. Yet in the years since these recommendations were made, yearly cuts in funding have compelled the CGAIR and many NARS to overall reduce their research agendas. With the decrease in donor funding, priorities, therefore, must shift towards enabling a better private sector investment environment to meet the needs of the medium and larger scale farmers, thus enabling the CGIAR and NARS to focus their activities on the poorest and most disadvantaged. The reality is that even that research investment is stagnant at best. Whether or not the public sector can seize opportunities and build upon private sector investments already made will, to a large extent, depend on the policies being pursued by governments today.

Some proposed concepts tend to follow along the lines of classical government capacity building and policy development activities. While that may at first consideration seem an inappropriate response to the new challenges of biotechnology, it should be remembered that biotechnology is more a continuation of past technologies (albeit with seemingly deeper consequences) than an entirely new departure. By extension, it seems likely many of the same problems and impediments are extended as well.

It is important to note that any research conducted on current biotechnology applications already commercialized (the so called first generation of products) and policies favoring their adoption will lead to faster adoption of the economically and nutritionally much more important second generation of products.

The proposals are organized as follows. For each proposed initiative, an objective is first identified and the rationale described. Subsequently, the process or processes for implementing the objective(s) are discussed, followed by the identification of instruments for its/their achievement. The order is arranged according to the overall degree of complexity of the subject but should not be taken as indicative of any prioritization.

Current activities and interests by both the private and public sectors in Latin America indicate that none of the proposed initiatives here will be duplicate or significantly overlap with current activities and investments. For program delivery purposes, proposed initiatives are described as either "process" or "instruments". Process refers to the procedures for accomplishing the strategic objective whereas instruments are the mechanisms, eventually to be institutionalized, for achieving them. In this way it is intended to be descriptive of both the broad objectives as well as means for realizing them.

5. Concept Proposals for Potential Biotechnology Transfer Support Activities

The activities proposed here are listed in order of complexity. All are directed towards increasing—directly or indirectly—the competitiveness of the agricultural sector, the agricultural biotechnology industry, and the underlying R&D capacity.

Note that whereas emphasis is placed on agricultural biotechnology, the proposed initiatives could, in most cases, easily be extended to animal health biotechnology and pharmaceuticals, as well as with some modifications to bioprospecting.

Also noteworthy is that different proposals may be implemented together or separately by different players. Each proposal clearly states strategies and thrusts and some functions may even be implemented in isolation of each other or mixed and matched between proposals depending on how their relative merit is viewed.

5.1 Encourage Governments to Implement Supportive Policies

Objective:

Provide an enabling environment for local and international companies to operate competitively in a transparent market. Only such markets instill confidence and trust through the participation of the local scientific and business communities, and the public at large.

Rationale:

Governments are in the “business”, among other functions, of providing enabling environments. Yet in many countries world wide there still is a total absence of coherent policies towards biotechnology and the components that facilitate transfer. This constitutes a tremendous impediment to biotechnology transfer.

The main responsibilities of governments can be grouped into five areas, namely:

1. **Coherent national biotechnology policy:** At the national level, a coherent biotechnology policy is essential to encourage public and private R&D and investments. At the international level, consistency will be critical in the development of negotiating positions and to meet international obligations.
2. **Provide incentives for R&D:** Encourage private-sector investment (local and international) through a fair tax regime, venture capital tax incentives, and repatriation of foreign exchange and other financial incentives.
3. **Ensure effective public awareness:** Governments must either establish or significantly contribute to a public awareness program from the outset that effectively communicates with the public about the rationale for decisions and the risks and benefits of crop biotechnology. The program should also encourage public participation in the decisions regarding the use of transgenic products.
4. **Establish effective biosafety and food safety regulations:** Build an efficient and transparent regulatory system that is science based and that meets international standards. The regulatory mechanisms must be implemented by credible institutions to enjoy a high degree of public confidence.
5. **Enact IP legislation to establish a regime consistent with legal obligations under WTO:** Protection of IP provides the economic incentive to the private sector (and in some cases to the public sector as well). With appropriate antitrust laws, enforceable IP protection encourages competition and leads to more products for farmers. IP is one of the major constraints to technology transfer.

Without coherent national strategies, a certain degree of R&D incentives, favorable public awareness strategies, effective regulations, and consistent IP regimes, any additional efforts are futile. The political economy of policy development requires for members of the professional community, including trade associations, to work with government officials in bringing about policy change. To what degree Latin American countries wish to strengthen their policies in the above five areas is a matter for sovereign decision.

Strategy:

1. Issue a conference statement and distribute it widely to senior policy makers, ensuring that policy makers are both aware of their role and responsibility in biotechnology and know the support activities offered by the professional associations.

2. Develop a strategy to follow-up with key policy-makers in each country, engaging them in a dialogue, effectively working with the future inside-government “champions” of biotechnology transfer.

Implementation:

What is proposed here is that the conference participants agree on a clear and concise statement to governments addressing the major issues. This is a very simple action to take and requires no additional resources. What is required is a commitment by key participants to be active at the national level after the meeting and engage policy makers in follow-up activities.

Other considerations:

It should be noted that the subsequent proposals given below would all influence and strengthen the policy making process through the generation and sharing of information, the development of successful case studies, and through the lowering of risks and barriers to technology transfer.

5.2 Coordinate Biotechnology Communication at the Regional Level

Objective:

Ensure that opinion makers (journalists, editors, community leaders), policy makers at all levels, and key decision makers in R&D administration and management, have access to up-to-date authoritative information and knowledge related to the need for and use of biotech applications, based on scientific facts, local cultural and social values, specifically targeting.

Rationale:

Access to information in the internet age is no longer an issue; what is a constraint is turning information into knowledge⁶. Policy makers and research managers, and others, more than ever before, are literally drowning in information. Yet up-to-date information, and knowledge associated with it (the practical meaning and implication of information), is much more difficult to come by. What is required is an information “digest” for those in decision-making positions because the competitiveness of any research and product development program depends on the comparative advantage it draws upon. The types of information and knowledge sharing will depend on the type of crops, namely commercial or non-commercial, and whether they are internationally traded commodities or not.

Whereas public perception and biotechnology regulations are often dealt with together, recent experience indicates that this has led to major problems in public acceptance. First, it is either the scientists, the regulators or the corporate executives/public relations experts who lead communication initiatives. All three have limitations (e.g. scientists have rarely been good at public communication), are perceived to be biased (e.g. companies evidently have a self interest in the information they diffuse), or have conflicts of interest (e.g. regulators cannot easily provide credible information that their regulatory approaches are strong enough).

Second, recent biotechnology communication strategies centered around the dissemination of facts and images; the latter in the dual sense of pictures (e.g. hungry children) and of positive corporate citizenship. Yet individuals respond to these only in the context of their cultural and social values. For example, for someone in Europe, where quantity and quality of food is plenty and where billions of scarce tax Euros are used to destroy surplus agricultural production, images of hungry children do little to further an understanding of biotechnology nor do they impress any particular interest nor feeling.

⁶ In John Naisbitt's words: “The world is drowning in information but thirsty in knowledge”.

Third, opponents to biotechnology from the non-governmental sector (NGO) have been particularly successful in influencing the media, the public and even the regulatory agenda because their campaigns tapped into and reflected local cultural and social values. In the US, for example, the movement against transgenic crops only gained some modest momentum when the issue of choice, or lack thereof, was debated in relation to the absence of labeling requirements. Choice and individual freedom are probably some of the most cherished virtues in the mind of US consumers (yet few really care in the US whether or not their foods contain products derived of transgenic crops).

What is needed is a concerted approach to biotechnology communication managed by a consortium of experts to ensure correct scientific information, professional communication to convey the appropriate image, and above all, tailor made to build upon and integrate the information with local values. Policy makers and the lay public is inundated with information and few have the time it takes to “understand” the key issues and implications for informed choices to be made. The proposal here would address this need.

Strategy:

Four thrusts are proposed:

1. Build communication and information access and exchange capacity in each of the participating countries to catalize and underpin effective local communication as well as local/national input into the strategy;
2. Prepare documentation and information packages in various forms to meet the needs of different target audiences (lay public, journalist, minister, etc.);
3. Establish a commodity based technology transfer information network; and
4. Undertake high profile targeted meetings, mainly in conjunction with visits of locally recognized world or opinion leaders as independent and credible voices

Thrust 1 would include compilation of electronic information, diffusion of key publications, fellowships to exchange people and personnel, compilation of the current and potential impact of biotechnology in Latin America, and the organization of specific information diffusion events.

Thrust 2 would include the preparation of short fact sheets and their translation into national languages, the preparation of illustrative studies and interviews, and the compilation of major news events and their meanings to the local situations. The information packages (ranging from less than one page for ministers to the inclusion of photographs for journalists) would be edited specifically for each target audience and distributed on a regular basis. Related to this the matter of prompt and appropriate responses in the case of a problem. Companies have found that a rapid and comprehensive response to problems ranging from oil spills to product recalls is the best protector of the good name of the company involved. Multinational companies nowadays have careful corporate plans in that regard. What they seem unprepared for is the Greenpeace-like action when all required steps/permits had been completed and no actual problems had emerged (witness the recent threatened action against Starbuck by Greenpeace in the US).

Thrust 3 essentially calls for the establishment of a “commodity technology transfer advisory group” with primary emphasis on information exchange related to commodities of regional importance. The concept is to identify working scientists from each group who will monitor their institution and report on the current situation, and work together with information clearing houses to place their institutional information into a wider concept. Much of the communication can be done building on the internet but some personal relationships must be established through periodic meetings. An EMail network can also be established among this group for answering questions and reporting experiences. Whereas there are major private interests in commodities in the region, at the moment at least few investments are made

into biotechnology transfer, partly because of the consumer acceptance constraints in Europe. For the time being, there will be little private sector development and only modest investments by public entities can be expected in the transfer of biotechnology to such commodities.

Thrust 4 would include short term visits by leading national, regional and international figures to facilitate well informed discussions with various constituencies, television, radio and newspaper interviews, panel discussions at universities and other locations, and meetings with consumer groups and advocates.

Implementation:

- a. Write a blueprint for the information consortium.
- b. Seek funding from stakeholders interested in biotechnology.
- c. Consider the needs for the establishment of a non-profit organization to serve as an umbrella, closely working with existing institutions (such as the national biotechnology for a, REDBIO and others).
- d. Develop a mission statement and operational strategy.
- e. Develop a slogan that captures the mission.
- f. Identify target audiences, contact details (media databases, etc.)
- g. Identify collaborators and national point contacts.
- h. Build a database of information sources, documentation, etc.
- i. Develop key messages to convey (identify, analyze key issues, review or conduct local survey on biotechnology perceptions, determine specific actions, test slogans with focus groups, etc.)
- j. Draft press releases, press interviews, placed articles, public awareness events, press conferences, reports and newsletters.

Estimated resource requirements:

Operational costs for the regional coordinating mechanisms should be small because the activities could draw heavily on existing institutions and endeavors, but would require at a minimum three to four full time writers and information experts. In addition, national focal points would require funding for operations and for specific events.

Funding options:

The institution should ideally operate with its own capital which could be a trust fund based on donations from stakeholder groups, including companies and existing biotech fora.

Other considerations:

Care should be taken to distance the endeavor from biotechnology companies, regulators and specific scientific institutions, as well as from existing biotech fora. Ideally, a new personnel should be hired not previously associated with biotechnology in any capacity. A strong link should be made informally with biotech stakeholders to ensure proper direction and sound information. For the commodity information network, this could possibly be implemented by REDBIO or other existing organizations and merely receive assistance from the proposed mechanism here.

5.3 Establish a Regional Brokering Service to Strengthen Public-Private Partnerships

Objective:

Establish a biotechnology broker service to facilitate biotechnology transfer, public/private partnerships and national IP portfolio management.

Rationale:

The number of biotechnology applications transferred to developing countries in agriculture that reach the final distribution stage to farmers have been few and far between despite significant efforts by many organizations, such as the centers of the CGIAR, NARS in many parts of the world and broker entities such as ISAAA, among others. Part of this is due to the long time it takes to develop new varieties of crops. Another reason is that biosafety regulatory mechanisms first had to be put in place with the concurrent human and institutional capacities. Further, until recently, few NARS had the scientific capacity to absorb transgenic technologies and build upon inventions and R&D already made by the private sector. All in all, the transfer has been slow despite significant investments.

At the other end of the spectrum are the corporations. One of their most scarce commodities is time and for companies to engage in biotechnology transfer—whether commercial or not—is still a novel practice and extremely time consuming. Broker services have invested significant time and resources in sensitizing companies to the need for and value of public/private partnerships and in developing a few pilot projects for demonstration and building of trust and confidence.

The third reason for the relatively slow transfer is the IP complexity of modern biotech products. Consider only the number of licenses required for Golden Rice discussed in sections 3.3.5 and 3.5 of the present document. As an example, licenses for 10 patents would be required for Brazil to cultivate Golden Rice in Brazil. This would possibly require licenses from the following entities (based on the patents issued in Brazil and original patent assignees):

- Centra National de la R.S.K.;
- E.I. DuPont de Neumours;
- Monsanto Company;
- National Research Council of Canada;
- Rhône-Poulenc;
- Syngenta;
- University of California; and
- University of Maryland.

This would require significant management time for the entity in Brazil who wishes to obtain the licenses and place a significant time burden on the companies. Further, and as a purely hypothetical example, if Brazil wished to export Golden Rice, say to the US, then an additional 20 or so product-by-process patents⁷ would apply for which licenses would need to be obtained. The point is that all of these transactions are time consuming and require specialized legal and licensing skills. Transferring such a

⁷ Claims may be worded to cover product *per se*, products-by-process, uses, or process. The first three categories of claims are of particular importance here because “product *per se*”, “product-by-process” and “use” claims generally extend to the products that embed the new discoveries. Hence export of products containing such IP can be impounded in the importing country unless licenses have been obtained. This is not the case with “process” claims or claims for the claimed technical procedures since they do not extend to the products that are produced by the claimed processes. Note, however, that the US Senate has been discussing for a while to pass a law that would make the import of products produced by process patents issued in the US a Federal offense.

bundle of ever increasing complex technologies also involves a major negotiating task, all the more because none of the standard practices of agreements have been developed. These are specific task a new regional broker should undertake to serve the specific needs in Latin America.

A complementary approach would be the development of equitable joint ventures between public and/or private sector entities from developing countries and private-sector organizations in industrialized countries. Such ventures could accelerate the adoption of tested technologies by farmers. Developing countries typically would contribute adapted germplasm and the partner company would provide the proprietary technology that enhances the germplasm. Building trust between parties to ensure an equitable partnership would become one of the key challenges and it is in this area where an independent broker institutions once again is critical to help build trust to achieve mutual objectives for both developing countries and the private sector. Both parties could make in-kind contributions to initiate projects and could agree on their respective returns after the economic value of the enhanced product has been evaluated in the field. Similar strategic alliances could also apply to germplasm developed by the NARS. Again, transactions would be complex and require, in addition to typical investment return calculations and agreement brokering services, valuation of germplasm.

In the medium term, NARS are also likely to contribute their own inventions and technologies and may wish to include them in deals made with foreign companies, possibly as a *quid pro quo* for accessing foreign technologies. Valuating such inventions and assisting in brokering the agreements once again require specialized skills.

The types of joint ventures described here in the agricultural biotechnology area are unlikely to be developed unless the smaller public and private entities in developing countries obtain broker services and support, possibly free of charge or at marginal costs only. Yet they have great potential for both the public institutions and local private companies in developing countries. They are particularly attractive to the latter, which normally lack the R&D and capital investments to develop their own technology. Joint ventures offer the opportunity to license the technology and gain experience with its use and distribution. The latter activity is one of the weakest links in the chain of crop production in developing countries.

In all of the above, a regional broker and IP portfolio management service offers many comparative advantages. Because of the specialized skills, contacts and experience required, it is unlikely that many countries would be able to find the funding to develop efficient and comprehensive services themselves.

Strategy:

Three thrusts are proposed:

1. Provide IP portfolio management services to public and private entities in Latin America;
2. Initially broker biotechnology transfer deals that meet primarily humanitarian needs in the region, gradually expanding into semi-commercial (and even commercial) deals; and
3. Develop, whenever possible, capacity building activities in institutional IP management.

Thrust 1 is related to the need to ensure that institutions manage their own and obtained IP in a most professional way possible. This instills trust and confidence and is considered a prerequisite for semi-commercial and commercial deals. This type of IP portfolio management service include an extended series of tasks, including assistance in the following areas:

- reconciling institutional policy and strategy development (e.g. staff policies and employment agreements, publication policy, assignment of ownership of inventions, etc.);

- institutional IP management (e.g. FTO reviews, lab notebook procedures, agreements management, internal TP management, compliance monitoring, etc.);
- technology valuation services (technology and germplasm); and
- assist in the protection of inventions (i.e. patenting).

It should be noted that technology valuation is a difficult process. The value of anything is more in the eyes of the beholder and depends on whether one is selling or buying something. When both the recipient and donor have experience in technology licensing, their respective excuses are a natural, although at times under-productive, part of the negotiation process. But if one party is relatively inexperienced (or perceives itself to be so or is perceived to be inexperienced), then the license negotiation process is slowed or may even break down completely. Establishing technology valuation models and offering credible intermediary services is of high value to all parties concerned. While various technology valuation models exist, the parties of a negotiation will seldom share their real valuation process for fear of revealing a critical business strategy. An honest broker is ideally placed to provide a germplasm and technology valuation service.

Thrust 2 is related to the need for professional assistance as a way of reducing transaction costs between parties. The broker service would act as a dynamic intermediary between technology donor and recipient; help establish, build and sustain trust among all parties involved; and solve current problems (and possibly undo existing constraints). The following services would be provided here:

- in- and out-licensing (e.g. develop negotiation strategies, drafting of Heads of Agreement, negotiation);
- develop template agreements for wide distribution such that a certain credible standard is established which will serve as a critical tool in capacity building;
- mediate between parties when they seem to have reached an impasse;
- arbitrate disputes; and
- serve as “expert witnesses” during dispute resolution proceedings.

Thrust 3 recognizes that biotechnology transfer activities and business development can only be sustained if institutional capacity exists. Each national partner involved in projects developed by the broker would still need to have limited internal capacity. This is a critical element in the strategy and much could be achieved through distance learning activities (such as *swift*Online, the distance learning workshop on IP Management; see www.swift.cornell.edu) and collaboration with a host of other institutions.

Finally, it should be noted that the service proposed here, although having attorneys on staff, would for a number of reasons not provide legal advice *per se* but coordinate legal inputs and opinions to be provided from qualified attorneys.

Implementation:

Whereas the specifics vary, the implementation strategy very much follows that proposed under 5.2 above.

Estimated resource requirements:

The feasibility study and blueprint should not be an expensive endeavor and could be implemented in the near term by a small team. Operating the service is a different matter and financial requirements will depend on the range of services eventually to be included. There are advantages in building up the service gradually but has the major disadvantage of not having a service with the necessary critical

mass for the range of complex legal and practical issues that need to be dealt with. As a broad estimate, the full service, when established, would require a minimum of US\$2-3 million per year and could service perhaps as many as ten deals consecutively. Note that for major joint venture and licensing deals to be completed, at least 1-2 years would be required whereas writing patents and valuating technologies and germplasm require significantly less time.

Funding options:

In today's climate of donor funding and priorities, it seems unlikely that new funds from the traditional philanthropic and bilateral donors could be obtained. Multilateral agencies, such as the IDB, on the other hand, should consider such a service as a high priority initiative because of its overall economic benefits to the region through the increases in agricultural productivity and farm income generation. The overheads of the service here proposed should be assumed by a multilateral donor with the users of the service paying at least the marginal costs. This would ensure fair treatment of all countries requesting the service without overloading the entity.

Other considerations:

Whereas there might be advantages in collaborating with existing broker services, such as the non-profit ISAAA or the commercial British Technology Group (BTG), this possible advantage would need to be balanced against the benefits of having a broker which specializes in the needs and operating modalities of Latin America. Neither of the services mentioned here could assume the range of services proposed here although the services may well be broken into smaller units. Finally, regional ownership of such a service might afford particular advantages but also requires diplomatic leadership to ensure equitable treatment of all member countries.

5.4 *Develop a Regional Biotechnology Investment Service*⁸

Objective:

Provide business investment services to local entrepreneurs, small companies and university researchers to facilitate biotechnology acquisition and biotechnology transfer from laboratory to market; leverage official development assistance (ODA) and foreign direct investment (FDI).

Rationale:

Biotech is a very high risk business as can be seen from the recent readjustments on the US stock exchange NASDAQ. It is essentially an equity type business with most exits from emerging market companies likely to be to trade players. The focus of biotech investments is mainly in North America, Western Europe and Israel where some biotech returns have been spectacular.

Whereas biotech in emerging markets is very much a sideshow as far as innovation and near term business opportunities are concerned, the technologies are likely to be exploited in a significant way only in the longer term unless specific initiatives are developed to accelerate investments. The near term need for biotech applications in developing countries are compelling, particularly in agriculture. Agriculture is of overriding economic and social importance in most emerging markets yet this has proven to be a source of poor returns in recent years.

It should be noted that the adoption rate of biotech crops in certain developing countries has nevertheless been impressive (e.g. Argentina, China, South Africa). There is also significant biotech research capacity in selected countries and the development of products in Cuba (vaccines), Mexico (seeds in general by Seminis, CINVESTAV's aluminum toxicity research) and Brazil (several crops). World class

⁸ This proposal benefited from inputs and comments by my colleague Andrew Hamilton.

scientific capacity exists in many public institutions but few have achieved biotechnology product development and market successes.

The emerging markets are also the setting for the exploitation of many industrial biotech applications, notably the use of fermentation technologies in antibiotics and biopesticides, biological systems for toxic substances removal in textiles, and the widespread use of tissue culture for the multiplication of horticultural crops (e.g. in Costa Rica for banana, Malaysia for oil palm, Kenya and South Africa for ornamentals). Tissue culture has been shifting away from Europe and Israel and there is evidence of some advanced engineering products in industrial production shifting offshore (e.g. precision agriculture). Over time, major biotech products are likely to increasingly originate from emerging markets notably soy products from South America, cotton from Asia, genomics services from Southeast Asia and China, and phytomedicine from Costa Rica. The proposal here is to significantly accelerate this trend.

Strategy:

Three thrusts are proposed:

1. "Marketing" investment opportunities from the region with potential investors.
2. Providing sustained quality deal flow, incl. investment advice and management services.
3. Work with investors for increased participation, incl. the Inter-American Development Bank (IDB) and national governmental agencies to leverage ODA (and ultimately Foreign Direct Investment or FDI).
4. Over time, an "investment company for development" could be created as a logical extension of the three thrusts proposed here.

Thrust 1 is related to the need for regionalization in business development and reduction of both risks and costs for investors and the costs for entrepreneurs to access capital. Many localized business services exist in Latin America which are generally physically located at business or technology parks within university campuses or in special industry zones. Few, however, are specialized in the unique services required for biotechnology where investor perceptions are somewhat different and where the technology is complex. What is needed is a regional service that exclusively specializes in biotechnology and assistance to local businesses, including ventures with multinational companies, and in investment deals.

Thrust 2 and thrust 3 are closely related to each other but require different approaches. Credible investment services can only be provided if well conceived feasible and lucrative investment opportunities are described and valued. Traditionally, business growth has occurred a) through mergers and acquisitions of operating assets, leading to short-term growth, or b) traditional market development *de novo*. Acquisition strategies for life science activities in developing countries have overall been unsatisfactory in many developing countries due to shortage of sound indigenous firms that are available for acquisition or licensing deals, compelling industry to the slow, expensive and risky process of development *de novo*. This limitation is particularly apparent in the agricultural biotechnology area with a dearth of medium-sized quality deals (those in the US\$2-10 million range), and with complications arising from management re-structuring, lack of trained managers, need for technological upgrading, and predictable exit strategies.

Increased ODA can play an essential role in these areas. Here the proposal is to develop the necessary conditions for leveraging ODA for biotechnology transfer. As is discussed under Proposal 5.2, one of the limiting factors is the lack of trained managers and business leaders in the agricultural biotechnology area. For that reason, FDI in general rarely reaches the poorer countries or the poorest segments of the population because the financial risks are generally too high (except for the purpose of natural resource extraction). On average, less than half of the developing countries attract international technology co-

operation and direct investment on commercial terms, and essentially none in agricultural biotechnology. ODA lays the ground for developing the necessary track record for private industry to follow on its own and leads to close collaboration between government and the private sector with the government lowering the commercial risks of the host country, thus creating favorable business climates.

Special training programs for entrepreneurs in biotechnology development are one of the initial instruments that forms the basis of technology cooperation. This is one of the thrusts of Proposal 5.2. Next are measures that would increasingly link ODA to FDI. This is a complex area and little is expected to take place in agricultural biotechnology for the foreseeable future without significant new programs and initiatives like the one proposed here. Hence the development of a few case studies in biotechnology, done well, will serve as learning and demonstration purposes. This learning process for development agencies and the private sector alike is an important factor in the largely uncharted area of commercial biotechnology transfer. Emphasis must fundamentally be placed on the transfer of scientific, technical and specialized managerial skills rather than hardware and traditional managerial skills. This will take a long term perspective and willingness to persevere by all partners.

Over time, ODA funds could be matched with FDI projects through joint ventures in biotechnology, initially in middle-income countries and later in lower-income countries. This could eventually shift to the provision of matching funds for FDI in the form of venture capital for technology transfer projects. If this approach succeeds, an "investment company for development" could be created as a logical extension of the three thrusts proposed here.

Implementation:

- a. Draft terms of reference for the study, comprising:
 - o investment scale and returns/risk analysis;
 - o sub-sector reviews inputs;
 - o sourcing deal flow: country studies, identification of financial investors and technology partners;
 - o form of investment options (conceptual and case study based, e.g. direct investor, investor in a fund, equity, loans, including types of businesses such as joint venture, public/private, virtual company, start-ups, licensing);
 - o develop specific services to be provided; and
 - o institutional options, strategy, priorities and funding.
- b. Establish a small team of experts with very strong technical and business skills in agricultural biotechnology and emerging markets.
- c. Conduct study and draft blueprint for a regional business development and investment service.

The starting point should be a cursory review of current national institutions providing investment services in the biotechnology and non-biotechnology areas and a review of external strategic factors. During the feasibility study, particular emphasis should be placed on the analysis of case studies, and the development of scenarios and model projects. Finally, a strategy for an investment service, including personnel requirements should be addressed with special reference to the knowledge intensive nature of biotechnology, the critical aspects of investment portfolio management, and the essential services that will have to be provided by the new entity (directly or in collaboration with other specialized entities).

The analysis could be conducted collaboratively by a small lead team (comprised of a specialist in international development and a business development expert) to be complemented by a small advisory group composed of senior individuals who will provide specific inputs, guidance and critical comments. Specialized case studies and expert reports could be purchased or commissioned.

Estimated resource requirements:

Work for a blueprint and detailed implementation plan is estimated at 6-9 person months and could be conducted over 6 months. The report would need to emphasize deal flow and case studies, on overarching medium term strategy and priorities for near term actions.

Funding options:

A consortium approach might be the most feasible comprising investment banks, regional development banks, private investors, and government agencies.

Other considerations:

The International Finance Corporation (IFC) is currently developing its biotechnology strategy and such a regional study would very well fit within that activity. A timely execution of the blueprint and consultations with IFC might lead to IFC placing priority to investments in Latin America.

5.5 Create an Integrated IP Escrow Service (Patent Pool)⁹

Objective:

Provide technology owners, the non-profit public sector and the small business community with a convenient, trusted and professional one-stop service to exchange IP and TP for humanitarian and semi-commercial needs.

Rationale:

Biotechnology donations for humanitarian purposes or for smaller semi-commercial markets rarely get completed. The examples of biotechnology transfer discussed under subsection 2.5, in the author's knowledge, have in no instance provided full Freedom-to-Operate (FTO); only partial licenses or donations have been brokered to-date. This is understandable in the ever increasing complex IP situation with but not quite satisfactory when product exports are contemplated. This complexity is one of the major impediments to biotechnology transfer to benefit small-scale farmers. Institutions like ISAAA, ABSP and even centers of the CGIAR have been able to broker licenses (or in the case of the CGAIR license in) major biotechnology components, such as IP and TP for insect resistance, virus resistance and more. But as the discussion on IP complexity and FTO under sub-section 3.3.5 above demonstrated, the first step of establishing who own which IP and TP is complex and tedious, not to mention obtaining licenses from each technology owner. This can be overwhelming for small companies, not to mention for the non-profit oriented CGAIR, NARS and universities in the North as well as in the South.

Surely, institutions like ISAAA and the CGIAR have made great advances in this by demonstrating the feasibility of such transfer. However, expanding the movement of private sector technology will require finding much larger mechanisms and substitutes for corporate management time.

In addition, researchers, especially those in the public sector, are often faced with uncertainty regarding access to given biotechnology components needed to distribute their research products. Some researchers have discontinued or re-aligned their research projects because of failure to access the required components. Other researchers have continued without appropriate licenses or even research-only agreements. In either case, valuable resources are ineffectively consumed.

This proposed IP Escrow Service would negotiate in advance with IP and TP owners license terms for humanitarian and for semi-commercial uses. Two complementary approaches are possible:

⁹ The concept proposed here has been developed in part with my colleague R. David Kryder.

- IP and TP for an the entire biotechnology product (e.g. a construct containing an insect resistance gene); and
- individual biotechnology components (CAMV 35S, co-transformation, biolistic gun).

In that way, researchers at universities, NARS and the CGIAR, as well as smaller businesses, could determine, in advance, which technologies were available to them and under what terms. This would assure the researchers of the availability of certain component parts and could formulate their R&D plans accordingly.

The IP Escrow Service would provide the research and international development community with a one-stop center to obtain a significant portion of technologies. Likewise, the service would provide technology owners and companies with a trusted, professional and efficient way to have their technologies deployed for humanitarian and semi-commercial purposes. Technology owners would be afforded an efficient and inexpensive way to expand the use of their technology for the benefit of the world's poor while not jeopardizing their legitimate licensing income. Once established and operating, the IP Escrow Service could also assume royalty bearing sub-licensing to small companies in industrialized and developing countries, which could provide technology owners with an added incentive to participate in the service. That would directly impact the efficiency of the Proposals described under 5.3 (Establish a Regional Brokering Service to Strengthen Public-Private Partnerships) and 5.4 (Develop a Regional Biotechnology Investment Service).

Strategy:

Consider establishing three entities, namely:

1. a Foundation which would hold the licenses and technologies
2. a brokering services addressing the humanitarian and capacity building needs, directly reinforcing Proposal 5.3; and possibly at a later date
3. a brokering services addressing the semi-commercial and commercial needs, directly reinforcing Proposal 5.4.

The rationale for Thrust 1 is related to the liability issues such an organization would face. This is a common thread that passes through the needs and concerns of all parties collaborating on such an institution (see also the discussion on risk shifting under 5.6 below) in regards to the specific liabilities that come from donating, receiving, or enabling the transfer of biotechnology. Risk of legal action occurs on several levels. There is the cost of defense, even if the legal action is eventually dropped or found in one's favor. Then there is the cost of defense and potential punitive (and other) damages if an action is found against a defendant. This concern about impending liabilities is not new, but with more publicity about significant legal actions, all parties would be raising concern. Clearly, a risk management strategy for such an entity would need to be set in place. This can take the form of the option proposed here, namely the construction of a "shell" entity¹⁰, the Foundation, which would serve as an organizational barrier constructed for three specific purposes:

- liability and risk shifting;
- tax reduction; and
- higher institutional efficiency and flexibility.

¹⁰ Examples of this are the joint stock companies of the 17th century and the proliferation of a wide range (Chapter "S" corporations, traditional corporations, limited liability partnerships, "off-shore" bank accounts, 501(c)(3) organizations, etc.) of such shields throughout history.

That shell organization, or Foundation, would exist to hold licenses and technologies, as appropriate, thus isolating various forms of risk from the different participants, including the corporate technology providers, the broker services and the recipients. The second reason, namely tax reduction, is related to mainly US corporate law whereby companies may donate funds and technologies to foundations and receive certain tax credits. This mechanism would encourage participation. The third aspect is related to the institutional policies and management structure for such as organization. Clearly, the needs would be different to the broker service described under Proposal 5.3 above, be it for purely humanitarian or semi-commercial needs.

Thrust 2 is related to the need to first establish a new model and develop the credibility and experience necessary to operate a broader entity for semi-commercial and commercial applications. The broker service, in conjunction with Proposal 5.3 for a broker, would increase the ability of public researchers at NARS and universities world wide to navigate and honor IP and TP rights, expand their access to proprietary technologies, all by reducing to a minimum the expense incurred by technology owners. In other words, transaction costs related to the donation of technologies will be reduced.

Thrust 3 directly assists technology owners in the management of their IP and TP, and finished products, particularly but not exclusively in regards to developing countries. The third entity, thus, would increase the licensing income of technology owners since the broker service would operate on purely commercial terms.

Implementation:

A full feasibility study would be required that places particular emphasis on investigating the possibility of whether such a patent pool would need to be global or whether it could operate efficiently at the regional Latin American level.

Specifically, the following issues would need to be addressed during the feasibility study and models would need to be developed, mainly in conjunction with technology owners:

- strategy to seek licenses for selected biotechnology components;
- modalities of sub-licenses;
- how to differentiate pre-granted licenses to public and private entities;
- types of sub-license to researchers for research only use;
- types of sub-licenses to public-sector researchers for commercial use;
- possibility for no-fee licenses for domestic use in selected developing countries;
- possibility for low-fee basis for domestic use in selected developing countries;
- modalities for export from/to selected developing countries (low-fee basis or no-fee basis);
- modalities of sub-license to private sector researchers for commercial use;
- which technologies/products could be “banked” (placed in the Technology Escrow Account);
- availability for which crops, traits, countries, etc.;
- definition of commercial, limited commercial and humanitarian use;
- liability and indemnification clauses for different recipients;
- qualification of sub-licensees, if any;
- criteria for accepting a technology/product;
- definition of developing country/ies;
- distribution of licensing income, if any.

In addition, the feasibility study would need to develop a blueprint for the organization(s), including options and recommendations as follows:

- a. prioritization of the functions and specific objectives;
- b. detailed short, medium and long term implementation strategies;
- c. structure, staffing, and location options;
- d. legal status and governance;
- e. possible institutional affiliation, bearing in mind that the entity would need to be neutral and
- f. impartial in order to be effective and credible;
- g. cost estimates for implementation of potential functions and specific objectives of the Facilitator with projections over the short-term and medium-term;
- h. the possible need for, and implications of a sunset clause; and
- i. funding options (e.g. fixed-term support versus core support; donor support group; not-for-profit versus commission-based; initial support versus longer-term options).

Estimated resource requirements:

The feasibility study could be commissioned to a team of experts in this area and should heavily rely on experienced managers in the related fields (e.g. draw on the expertise of entities such as Plant Bioscience Limited, the technology commercialization arm of the John Innes Center in Norwich, UK, among others). The study could be carried out by a team with a senior advisory board.

Funding options:

The Rockefeller Foundation sponsored a series of consultations through the Meridian Institute to investigate the role of the public sector and private sector in meeting food security needs with particular emphasis on the proprietary science management aspect. The foundation would possibly consider favorably a proposal for a specific initiative of this kind. The McKnight Foundation in the US has also shown interest in this area. These could at least be considered as possible sponsors for the feasibility study.

The Escrow Service per se would require substantial funds to be able to operate. Several million US\$ in annual expenditures would be required, partly because the staff would need to include several senior attorneys and licensing experts. It is not expected feasible to have the total costs covered by the users, even for the semi-commercial arm of the entity. For this, significant funds would be required and it is conceivable that such funds could either come from the IDB or through World Bank loans to national governments.

Other considerations:

The Escrow Service could be extended to also service the technology patenting and valuation needs of developing country institutions, either public or private. On the other hand, mixing the two services might lead to policy conflicts and may better be kept separate as proposed under 5.3 above.

5.6 *Elaborate on and Develop Initiatives for Risk Shifting*^{11 12}

Objective:

Minimize risks inherent in biotechnology transfer by providing specific government guarantees (in other words, reducing the risk of biotechnology transfer for those entities willing to transfer biotechnology applications).

Rationale:

Risk shifting is largely a pooling matter which is an ideal activity performed by government. That is, to use life insurance as an example, the individual is really betting he/she will die young. In individual cases that may indeed occur, but insurance companies can balance those costs against the probability many clients will live a long time. Risk absorption is possible because it is spread across a large group. Similarly, companies often see major risks of loss when entering new markets, such as developing countries. Governments can help minimize those risks by providing specific guarantees. Presently many countries guarantee their national companies against loss of entering trade shows (if new sales do not exceed the cost of participation then the government reimburses the difference) and foreign companies are often provided export guarantees (through national bank involvement and related instruments such as secure credit). The particulars to encourage biotechnology transfer would be different, but conceptually the governments in the region could provide similar guarantees in the case of biotechnology transfer. This could also be assumed by regional entities such as MERCOSUR.

In biotechnology transfer, three dimensions of risk are prevalent, namely:

- financial risks of loss;
- liability risks; and
- risks related to public relations (discussed above, Proposal 5.2).

Any transaction involves risk so the particular point being made here is that with the newness of biotechnology, the nature and extent of the risks are really unknown. This is a deterrent to trading, especially if the market potential is small. In cases where companies are considering donations for use by smaller scale farmers or in semi-commercial markets, these risks often have led companies to conclude that participation is too risky. The proposed action is therefore directed to shifting risks away from the company to other entities, possibly including national governments in Latin America.

Strategy:

Two thrusts are proposed:

1. Develop and establish (i.e. institutionalize) financial instruments:
 - a. to subsidize transactions thereby reducing private costs and the potential and scope of loss;
 - b. to make up losses after the fact; and
 - c. to spread risk through joint ownership.
2. Develop and establish (i.e. institutionalize) liability instruments:
 - a. to provide insurance in case of mishaps; and
 - b. to transfer ownership (since liability comes with ownership).

¹¹ This directly complements the Proposal under 5.4 (*Regional Biotechnology Investment Service*) but the proposed initiative here is aimed at government action.

¹² This proposal had originally been developed in a somewhat different form together with my colleague William H. Lesser.

Financial Instruments

Thrust 1 on financial risks is based on the rationale that if the risk/return balance is unfavorable, companies will not enter a market. In the authors experience, companies feel that small markets have generally higher levels of risk than large markets, and also offer a smaller potential pay out. That is, market development involves many fixed costs and other costs which are not proportional to the market size. It has been a long time practice of governments to encourage their industries to enter new markets by providing guarantees against loss. From a private sector perspective, participation in a trade fair for example is nearly without risk. But trade fairs are not well suited to intermediate technologies like biotechnology, but investments can be underwritten or guaranteed.

Financial risks are relatively easy to compensate for as they are clearly defined. In all these areas the government presently has or is planning activities which could be shaped for the purposes here. Subsidies can be approached through loan guarantees, guarantees which either reduce the cost of capital by providing a secure creditor or which make repayment based on conditions based on the success of the project¹³. Loan guarantees are more appropriate for small to medium sized companies and hence are not clearly indicated for the large, well financed companies in biotechnology. Loan performance requirements are really a non-symmetric joint venture in which the governments would not directly benefit from success¹⁴ but would share the costs in the event of a loss. Those loans could be arranged through the existing government departments and programs although considerable redrafting of objectives would seem to be required in many countries.

The means for these risk shifting schemes are to invest in a minority share in the establishment of local infrastructure necessary to enter the markets (market representatives, training, physical distribution, etc.). As the minority shareholder the fund may have to act as a secondary creditor receiving returns only after the private sector investment is partially or fully recovered. Monies for these kinds of activities have previously been allocated so that no new project formulation is required.

Liability Instruments

Thrust 2 on liability instruments is based on the rationale that companies are increasingly being held financially accountable for the damage caused by their products. Often the cases are directed to the wealthiest of the involved entities, even if the problem was more one of improper use than the product characteristics, the so-called "deep pocket" approach to damage recovery. Thus cases of alleged ground water pollution from agricultural chemicals often involve the manufacturer of those chemicals as well as the direct users. Furthermore, cases may be brought on a class action basis anywhere in the world, such as the home country of the company rather than where the damage was caused. All this has made companies extremely aware and sensitive to potential liability. To date there have been no liability cases associated with alleged environmental damage caused by transgenic organisms, but that is no assurance they will not occur at some point in the future. Indeed, the matter may be more uncertain prior to any law suits as the potential acceptable grounds and apportionment of joint liability are completely unknown.

From a corporate perspective, market opportunities with limited profit potential—or more so, no potential in the case of donations—an open-ended liability will be sufficient to end the interest and therefore

¹³ In the case of biotechnology transfers whereby governments take on licenses on behalf of their national agricultural economies (see Proposal 5.3), success could be measured in terms of percentage adoption rates or savings in foreign currency for the importation of pesticides.

¹⁴ Although this is correct, governments still benefit through increases in agricultural productivity which, in turn, leads to higher tax revenues.

the transfers even for humanitarian purposes. Governments can rebalance the matter by shifting risk from the companies using procedures discussed above.

Presently there are major insurance companies providing various forms of environmental insurance; the other option for large companies is self insurance. These are highly technical matters which are not conducive to government involvement. However, it should be noted that insurance operates on a pooling (averaging) basis. While a risk pool covering applications not provided by private insurers for companies would be unfeasible due to the limited number, it is possible to consider a multi-country pool. Certainly, other countries are faced with the same issues regarding the private sector and may wish to join an insurance program.

The matter of shifting ownership is somewhat more straightforward. The most appropriate owner in the case of a donated technology would be the recipient government or government agency. With ownership at the time of any accident clearly that of the government, it would be difficult to ascribe responsibility to a previous owner. Alternatively, a government agency could become the owner of record, in either case the government making the necessary agreements.

Implementation:

- a. Establish a consortium of business schools and law schools in prime universities in Latin America, review risk shifting approaches in other sectors and develop the concepts, together with industry, and adapt approaches to national law and customs.
- b. Convene round tables with senior policy makers and department of finance officials in a select number of countries as a way of refining the concepts and lobbying for their implementation.
- c. Explore options of working with regional bodies such as MERCOSUR and a few progressive governments willing to implement schemes on a trial basis.

Estimated resource requirements:

The proposals could be developed with little funds and be implemented as part of current university and government activities.

Funding options:

A specific roundtable could be financed with assistance from the IDB or World Bank.

6. Conclusions and Options for Follow-up

Given the current worldwide emphasis on privatization, there is a mood of minimization for the proper actions of government. The approach and options proposed here in many ways support that view. There are no new proposals for direct government action in technology transfer. Governments are not effective at such things; they are better left to the inventors, the businesses and the users. What governments are effective at is broader, longer term activities, those beyond the scope or planning horizon of the direct participants. The proposals suggested here are of that nature. Some could be done by, and perhaps should be done in conjunction with, NGOs (e.g. information exchange, capacity building). Others could be done by private entities.

The first formal action planned for utilizing this document is a regional conference in Montevideo, Uruguay, 28-30 March 2001, convened by the Regional Biotechnology Forum. Participants will include government representatives, industry, researchers, international organizations and other relevant experts. That meeting can be used to prioritize the transfer support activities proposed in this briefings paper.

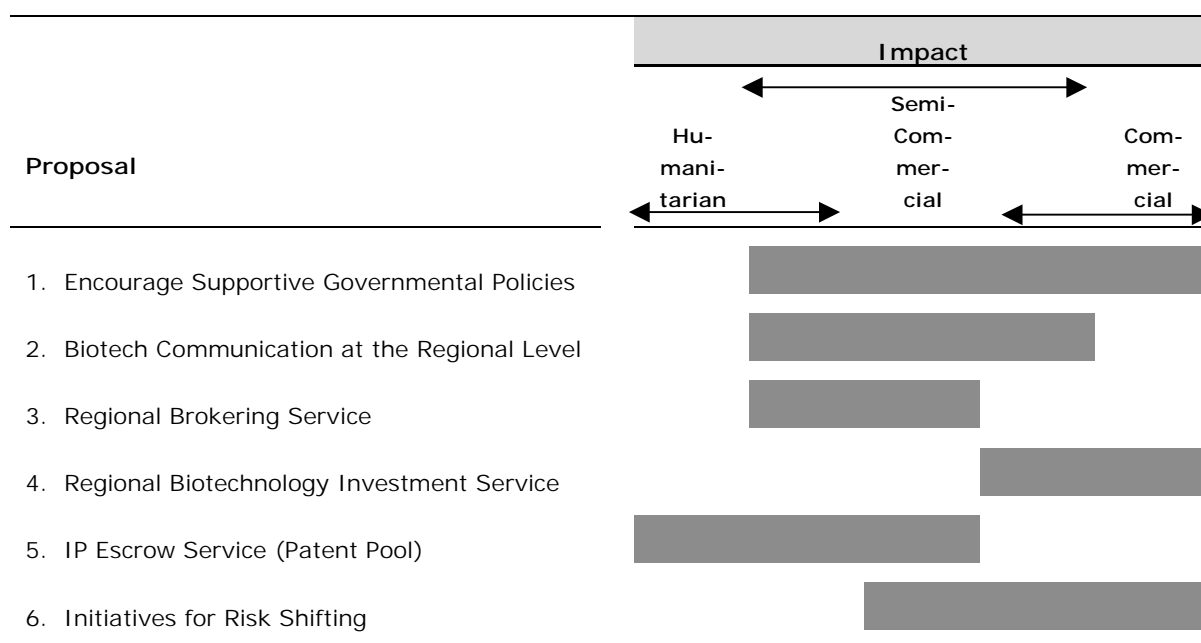
Prioritization can be done in several dimensions based on perceived usefulness, feasibility of achieving goals, availability of personnel and financing, and political considerations.

Individual proposals could also be modified to meet somewhat different needs; much will depend on the priorities assigned by the region to the different objectives and constraints. Figure 2 lists the six proposals and demonstrates where their impact would be in terms of increased biotechnology transfer activities. The figure is based on the here proposed strategies but the mandates of the different initiatives could easily be extended or reduced, or shifted in one direction or the other, recognizing that there is considerable overlap in the different areas.

If the Regional Biotechnology Forum makes a decision to proceed with any of the proposals, then a follow-up planning group meeting led by individuals and institutions who might implement activities might be an effective means of getting initiatives underway. To be considered for inclusion are needs perceptions by participating country representatives and the identification of industry and other partners. Many of the proposals made here require significant coordination.

The key step is the identification of individuals and institutions to initiate and implement the programs. While all have been structured not to place great responsibilities on any individual and institution, still the key personnel will be instrumental in any substantive steps taken.

Figure 2: Primary Impact of Proposed Initiatives



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Appendices

I. A Note on Definitions

“Intellectual Property” (IP) has been taken to mean, without limitation, intellectual property rights, including patent rights, plant variety protection certificates, unpublished patent applications, and any inventions, improvements, and/or discoveries that may or may not be legally protectable, including all know-how, trade secrets, research plans and priorities, research results and related reports, statistical models and computer programs and related reports, and market interests and product ideas.

“Technical Property” (TP) has been taken to mean, without limitation, computer software, germplasm and the biological materials and derivatives thereof, and related information.

“Proprietary Property” (PP) is Intellectual Property and Technical Property and Information.

“Humanitarian”, “Semi-Commercial” and “Commercial”

Humanitarian needs are here defined as meeting the needs of primarily resource-poor and subsistence farmers who generally operate outside market economies. This is in contrast to “commercial” uses. In between these two are the “semi-commercial markets” which are defined as those in between the purely humanitarian or small-scale subsistence farmers needs, and those of direct interest to seed companies.

This semi-commercial market is believed to be an important sector in Latin America.

“Humanitarian” in Licensing Agreements

It should be noted that in any licensing agreement, it is extremely difficult to define what precisely “humanitarian” or “non-commercial” means. Even subsistence crops are traded or bartered and thus constitute a commercial activity. Perhaps the distinction lies not so much in “no-commercial” (since subsistence farmers are eager to become surplus producers, but in the proportion of the harvest which is consumed. It is proposed that if a farmer consumes more than 50% of the crop, then it is a subsistence farmer/crop.

II. List of Abbreviations and Acronyms

ABSP	Agricultural Biotechnology for Sustainable Productivity
ACR	Agribiotecnologías de Costa Rica SA
APHIS	Animal & Plant Health Inspection Service
ASEAN	Association of South East Asian Nations
BBSRC	Biotechnology and Biological Research Council
BINAS	Biosafety Information Network and Advisory Service of UNIDO
BTG	British Technology Group
CAMBIA	Center for Agricultural & Molecular Biotechnology in International Agriculture
CARN	Cassava Advanced Research Network
CAS	Central Advisory Service
CBD	Convention on Biological Diversity
CBN	Cassava Biotechnology Network
CENARGEN	Centro Nacional de Pesquisa de Recursos Genéticos e Biotecnologia
CGIAR	Consultative Group on International Agricultural Research
CIAT	Centro Internacional de Agricultura Tropical
CIMMYT	Centro Internacional de Mejoramiento de Maíz y Trigo
CINVESTAV	Centro de Investigación y de Estudios Avanzados
CIP	International Potato Center
CNPMF	National Center for Research on Cassava and Tropical Fruit
CNPMS	Centro Nacional de Pesquisa de Milho e Sorgo
CNPQ	Conselho Nacional de Desenvolvimento Científico e Tecnológico
DANIDA	Royal Danish Ministry of Foreign Affairs
DGIS	Directorate General for International Cooperation of the Netherlands
ELISA	Enzyme-Linked Immunosorbent Assay
EMBRAPA	National Agricultural Research Corporation of Brazil
EPA	Environment Protection Agency
EPC	European Patent Convention
FAO	Food and Agriculture Organization of the United Nations
FDA	Food and Drug Administration
FDI	Foreign Direct Investment
FTO	Freedom-to-Operate
GATT	General Agreement on Tariffs and Trade
GEF	Global Environment Facility
IARCs	International Agricultural Research Centers
IBS	Intermediary Biotechnology Service
ICGEB	International Center for Genetic Engineering and Biotechnology
IDB	Inter-American Development Bank
IDRC	International Development Research Center
IFC	International Finance Corporation
IFPRI	International Food Policy Research Institute
IICA	Inter-American Institute for Cooperation on Agriculture
IITA	International Institute of Tropical Agriculture
INBio	National Biodiversity Institute of Costa Rica
INTA	Instituto Nacional de Tecnología Agropecuaria
IP	Intellectual Property
IP/TT	Intellectual Property/Technical Property
IPR	Intellectual Property Rights
ISAAA	International Service for the Acquisition of Agri-biotechnology Applications
ISNAR	International Service for National Agricultural Research
MERCOSUR	South American Common Market
MTA	Material Transfer Agreement
NARS	National Agricultural Research Systems
NGO	Non-Governmental Organization
ODA	Official Development Assistance
PBRs	Plant Breeders' Rights
PLRV	Potato Leaf Roll Virus
PROCISUR	Programa cooperativo para el desarrollo tecnológico agropecuario del cono sur
PVP	Plant Variety Protection

PVX	Potato Virus X
PVY	Potato Virus Y
R&D	Research and Development
REDBIO	Red de Cooperación Técnica en Biotecnología Vegetal of FAO
RFLP	Restriction Fragment Length Polymorphism
SDC	Swiss Agency for Development Cooperation
SEI	Stockholm Environment Institute
SWIFTT	Strategic World Initiative for Technology Transfer at Cornell University
TAC	Technical Advisory Committee
TP	Technical Property
TRIPs	Trade-Related Aspects of Intellectual Property Rights
UN	United Nations
UNDP	United Nations Development Program
UNEP	United Nations Environment Program
UNIDO	United Nations Industrial Development Organization
UPOV	International Convention for the Protection of New Varieties of Plants
USAID	United States Agency for International Development
USDA	United States Department of Agriculture
WBCSD	World Business Council for Sustainable Development
WIPO	World Intellectual Property Organization
WTO	World Trade Organization
WWW	World Wide Web

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