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Consultative Group on
International Agricultural Research

Intellectual Property Issues for the International Agricultural Research Centers

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ISSUES IN AGRICULTURE 4

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About the CGIAR

The Consultative Group on International Agricultural Research (CGIAR) is an informal association of 40 public and private sector donors that supports a network of 16 (soon to be 17) international agricultural research centers. The Group was established in 1971.

The World Bank, the Food and Agriculture Organization of the United Nations (FAO), and the United Nations Development Programme (UNDP) are cosponsors of the CGIAR. The Chairman of the Group is a senior official of the World Bank which provides the CGIAR system with a Secretariat in Washington DC. The CGIAR is assisted by a Technical Advisory Committee, with a Secretariat at FAO, Rome.

The United States, Japan, and Canada are the leading donor countries, followed closely by several European countries. Developing country members of the CGIAR are China, Brazil, India, Mexico, Nigeria, the Philippines, and the Republic of Korea. The annual CGIAR budget is some $US300 million.

International centers supported by the CGIAR are part of a global agricultural research system. The CGIAR functions as a guarantor to developing countries, ensuring that international scientific capacity is brought to bear on the problems of the world's disadvantaged peoples.

Food productivity in developing countries has increased through the combined efforts of CGIAR centers and their partners in developing countries. The same efforts have brought about a range of other benefits, such as reduced prices of food, better food distribution systems, better nutrition, more rational policies, and stronger institutions. CGIAR centers have trained over 45,000 agricultural scientists from developing countries over the past 20 years. Many of them form the nucleus of and provide leadership to national agricultural research systems in their own countries.

Programs carried out by international centers in the CGIAR system fall into six broad categories: Productivity Research, Management of Natural Resources, Improving the Policy Environment, Institution Building, Germplasm Conservation, and Building Linkages.

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EXECUTIVE SUMMARY

Many of the International Agricultural Research Centers are increasingly concerned about whether they ought to protect their innovations as intellectual property, a protection they have rarely sought in the past. Three developments feed this concern: (1) The rise of biotechnology and its growing importance for the centers' research; (2) the "privatization" of agricultural research, meaning the increasing importance of private industry in agricultural research as well as the growing practice of public research institutions of protecting their innovations against use by unauthorized third parties; and (3) the tightening of national and international legislation and conventions that protect intellectual property.

This study has been commissioned by the CGIAR Secretariat, in consultation with the Chairman of the Center Directors Committee. Its purpose is to review whether the above concerns suggest a need to modify the current "open-door policy" of the centers with respect to

germplasm distribution and the release of innovations developed at the centers, and, more broadly, to evaluate the options available to the centers.

The study reviews the trends in biotechnology research and in intellectual property law described above. It then considers the factors affecting four policy issues for the centers, both in general and in the context of specific categories of centers:

- To what extent can the current open-door policy be retained?
- What is the feasibility of income generation from patenting and licensing?
- Would proprietary protection hinder or help in bringing research results to the farmer?
- What are the benefits and risks of cooperating with developed-nation industry to obtain access to patented biotechnologies?

Our review leads to the following conclusions:

1. The trend within the international research community to protect intellectual property has advanced too far to be ignored by any CGIAR center. The centers will increasingly find that technology they need is subject to intellectual property protection and that an effective way to disseminate their innovations will be through private sector collaborators, often under exclusive rights. Moreover, as many developing countries are likely to adopt or strengthen intellectual property protection over the next several years, breeders will seek protection also in developing countries for advanced material of importance to their markets in both industrial and developing countries.

2. Much of the activity of the centers can continue without intellectual property protection and without breaking with the centers' traditions of open scientific

exchange. This will be particularly true for centers working in countries that have not extended intellectual property protection to plants and biotechnology and for centers whose mandate crops have little commercial interest for industrial country markets.

3. Under current policy, centers should not restrict the flow and release of *unimproved* germplasm including germplasm which has been screened and characterized. They may wish to consider changing to a policy of safeguarding their bargaining position by requesting a material transfer agreement to be routinely signed by institutions that will not reciprocate a center's free exchange policy. In contrast, centers may consider licensing their *improved* germplasm to breeders and producers who intend to market it in industrial countries with little or no additional breeding.

4. Only rarely will intellectual property protection and commercialization in industrial countries be a lucrative option for the centers. However, centers scoring research advances in areas of high commercial interest should consider acquisition of patents in industrial countries, not so much as defense against seeing their innovations appropriated by third parties (that is better done through publication) but as bargaining chips to maintain access to proprietary technologies. There might be cases in which a center should patent an exceptionally important invention as a source of income, but these would be rare.

5. As it will be imperative for the centers to continually gain access to new proprietary technologies of potential use to developing countries, they will require understanding of patents and licensing; acceptance of commercial materials subject to restricted use will also entail acceptance of restrictions on the free intersystem exchange of materials.

6. Finally, each center should carefully review the institutional linkages by which its innovations reach the farmer and should protect its innovations when such

protection is likely to help in marketing the innovations to developing country farmers.

In order to help the centers in defining and executing such policies, we recommend that:

1. The CGIAR should establish a set of intellectual property policies and guidelines, within which individual centers would define their own rules and procedures. Such a Policy Statement should lay down the ground rules to which the centers will adhere when structuring their "upstream" relations with technology providers and research collaborators. It might also sketch out the new partnerships centers are looking for in their "downstream" relations with breeders and the seed industries in developing countries. The Policy Statement should consistently reflect the position the Group and its centers take on related issues (e.g., on genetic conservation and biodiversity) and should therefore also serve to contain the risk that expanding intellectual property protection will eventually slow the flow of germplasm.

2. Individual centers should draw up their own rules and procedures to provide for:

   i. germplasm distribution;

   ii. standard networking arrangements likely to be needed to bring in outside technologies and — to the extent reasonably predictable — the kinds of proprietary restrictions that may be accepted, and of center innovations they would consider patenting; and

   iii. in-house procedures for controlling proprietary information, employee agreements, relationships with patent counsel, periodic reviews of intellectual property changes in host and other countries, and reviews of intellectual property trends affecting their mandate crops.

3. At least in an initial phase, and until centers have built up sufficient capacity to manage their intellectual property, they should consider the creation of a central facility to provide basic advice and to refer centers to legal counsel appropriate to their specific concerns. Such a facility should also allow centers and their staffs in charge of intellectual property management to exchange information and experiences on patent and plant variety matters. During the start-up of this new activity, centers should arrange, perhaps with the help of other international agencies and intellectual property groups, workshops to help their scientists, their staffs working on intellectual property issues, and their colleagues from national programs to understand the basic concepts as well as the costs and benefits associated with intellectual property, and to ensure that the technical aspects of the law not hinder their mission.

The study also includes Annexes outlining in-house policies and procedures for implementing a patent program and a tabulated overview of intellectual property protection in developed and developing countries.

I. INTRODUCTION

Through their research, the International Agricultural Research Centers are continuously generating innovations. This was true before the advent of biotechnology; it is true today for biotechnological advances. The breeding of high-yielding varieties of wheat and rice that marked the "Green Revolution" generated innovations just as do today's much broader activities of a larger number of centers aimed at sustained yields in environmentally sustainable conditions. Biotechnology has since added a new dimension: it permits procedures that

cannot be achieved through conventional breeding, like inserting a single new gene without otherwise modifying the original genotype or variety; and it can greatly shorten the time it takes to achieve breeding results through conventional means.

Today, the centers are increasingly concerned about protecting their innovations as intellectual property, a protection they have rarely sought in the past. Three developments feed this concern: (1) the rise of biotechnology and its growing importance for the centers' research; (2) the "privatization" of agricultural research, meaning the increasing importance of private industry in agricultural research as well as the growing practice of public research institutions protecting their innovations against use by unauthorized third parties; and (3) the tightening of national and international legislation and conventions that protect intellectual property.

This study has been commissioned by the CGIAR Secretariat, in consultation with the Chairman of the Center Directors Committee. Its purpose is to ascertain whether the above concerns suggest a need to modify the current "open-door policy" of the centers with respect to germplasm distribution and the release of innovations developed at the centers, and, more broadly, to evaluate the options available to the centers.

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II. PAST EXPOSURE OF THE SYSTEM TO INTELLECTUAL PROPERTY ISSUES

The centers and the CGIAR have been slow in addressing intellectual property concerns. A review by TAC in 1982, well before plant patenting became an accepted

proposition, and therefore reflecting only on the usefulness of plant breeders' rights[1] concluded that because of the breeders' exemption anchored in the International Union for the Protection of New Varieties of Plants (UPOV) Convention there was no reason for the centers to be concerned about possible constraints to be imposed on the centers' access to germplasm. And as centers moved increasingly into strategic research, and therefore produced less finished varieties, the problem would lose its relevance. On subsequent occasions the debate was deferred pending resolution of uncertainties arising from the various endeavors to modify the UPOV Convention and negotiations in the General Agreement on Tariffs and Trade (GATT).

In 1988, the CGIAR issued a Policy Statement on Plant Genetic Resources which espouses an open-door policy with respect to the safe maintenance of germplasm and its availability to crop improvement programs. Under this policy, centers distribute germplasm from their active collections to any researcher who demonstrates a legitimate interest; the centers make no attempt to exercise control over subsequent commercial use of such germplasm.

The 1989 Biotechnology Study cosponsored by the World Bank, the International Service for National Agricultural Research (ISNAR), the Australian Centre for International Agricultural Research (ACIAR), and the Australian International Development Assistance Bureau (AIDAB)[2] suggested that centers should actively seek

[1]In this paper, we use the term "patent" to refer to the regular or utility patent system. We use the terms "plant variety protection" and "plant breeders' rights" interchangeably. Both denote protection of the right of the breeder to market a new variety which is distinct, uniform, and stable, and generally include both sexually and asexually propagated varieties. In the United States, the nomenclature has developed differently, as asexually propagated varieties are protected by "plant patents," while sexually propagated varieties are protected by "plant variety protection" (see also discussion in 'The Changing Legal and Political Environment').

[2]G.J. Persley. Beyond Mendel's Garden: Biotechnology in the Service of World Agriculture. C.A.B. International 1990. Pages 105,106.

patents for their significant discoveries, either to control their use by others, or to earn royalties. Patent ownership would be critical in negotiating collaborative arrangements with private biotechnology companies. The study also saw a role for international development agencies and for the centers to negotiate access to technology on behalf of small countries or groups of small countries that otherwise would not have access to new technologies. The study cautioned, however, that intellectual property protection for germplasm not be strengthened to the point where research is inhibited.

The Netherlands' Foreign Ministry recently commissioned a study on "The Impact of Intellectual Property Protection in Biotechnology and Plant Breeding on Developing Countries."[3] While proposing a cautious approach for developing countries in adopting intellectual property protection, it suggested a need for the international centers to seek patent protection in order to facilitate collaboration with the private sector; to prevent the appropriation of publicly funded innovation by third parties; and eventually to seek earnings from royalties in order to compensate for shrinking public funding.

To date, few centers have been exposed to intellectual property issues. In response to a query by the CGIAR Chairman in November 1989, only five centers indicated that they had experience with managing intellectual property. Two centers had patented farm equipment or fertilizer preparations; one shared a patent with a collaborating institution in a developed country; the other two had filed for patent protection, one for a variety, the other for a biotechnologically developed vaccine. One center is exploring the possibility of filing, jointly with a public agricultural agency in a developed country, for plant variety protection for one of its varieties.

The rationales provided by these centers for seeking protection differed: four centers had filed for patent

[3]Study commissioned by the Directorate General International Cooperation (DGIS), Ministry of Foreign Affairs, The Hague, Netherlands, January 1991 (mimeo).

protection in order to control the subsequent use of the innovation (what they viewed as "defensive patenting"), one center saw potential for generating revenue, while one center intended to have a private sector collaborator take over product development and marketing.

Pressure has recently mounted on the CGIAR and the centers, from within governing boards of some centers and from some donors, to define policies for the CGIAR on intellectual property issues.

In November 1990, ICRISAT and the CGIAR Secretariat cosponsored a workshop on intellectual property issues and their relevance to the centers. Representatives of several centers and a number of experts attended. The workshop's report argued that the institutional and legal environment in which the centers operate has changed in a lasting fashion, and that the centers have no options but to adjust to the new environment. The report provided detailed suggestions on how centers might manage intellectual properties (ICRISAT, 1990; also see Annex A).

III. CHALLENGES TO CURRENT CENTER POLICY

A. The Rise of Biotechnology

1. Facts and Promises

The breeding techniques which have been responsible for the advances made under the "Green Revolution" will not be sufficient to feed the world's growing population in the next century. According to current estimates, food production in developing countries will have to double in the next 25 years to keep pace with population growth (IFPRI, 1988). Given the finite availability of land and water, future increases in agricultural production will have to come from new technologies that

enhance productivity. Biotechnology is widely seen as the technology, and perhaps the only one, that can launch another "Green Revolution."

Developments in biotechnology over the past decade have often been accompanied by exaggerated claims of their potential impact on agricultural production (World Bank, 1990, p. 14). Among the few products about to reach the market which promise a substantial impact on production are growth inducers for animals (somatropin) and some disease controlling vaccines (Lesser, 1990, p. 65). Cautious estimates on future yield increases due to biotechnology by the Office of Technology Assessment of the U.S Congress in 1986 (OTA, 1986) expect productivity gains to be two to four times higher than those that could be achieved with conventional breeding techniques.

A variety of specific technologies have arisen under the general name of new biotechnologies. The most widely used, tissue culture, is itself a group of technologies which can be used to eliminate viruses from organisms, to shorten breeding and distribution times for new cultivars, to provide accelerated processes of selection, new sources of genetic variation, and new techniques of conserving germplasm. Breeding can also be accelerated through genetic markers and through use of gene maps based on restriction fragment length polymorphisms (RFLP). Monoclonal antibodies can assist in detecting the presence of specific proteins.

What appears to be most revolutionary in the near future is the ability to manipulate DNA to transfer specific genes from almost any species to almost any other species. The recombinant DNA technique permits, for example, the development of plants that produce an insecticide based on a bacterial gene *Bacillus thuringensis*. In the long run, even these accomplishments may be dwarfed by approaches based on the insights gained from using these new techniques, e.g. cloning, and research on plant and animal physiology.

2. The Importance of Biotechnology for Center Research

A move away from hands-on applied research toward strategic research is well underway in most centers. It has been aided by two factors: First, at a time when increased crop yields have decreased the immediate danger of famine, the centers have been able to take a longer perspective. Second, in many developing countries national research institutions have built the capacity to finish and adapt intermediate material provided by the centers to local conditions.

In this context, most centers have embarked on biotechnology programs. However, with annual biotechnology expenditure in 1990 estimated at $14.5 million of which about half was for animal biotechnology (Collinson and Wright-Platais, 1991, p. 9), these programs appear modest. They are likely to increase in future as some centers, in order to maintain their role as centers of excellence and facilitate transfer of technology to developing countries, will move closer to the leading edge of biotechnology to match advanced industry and university laboratories in the industrial countries in research quality and direction; while other centers who understand their function primarily as that of a catalyst, stimulating and supporting research at other institutions, and adapting it for the needs of developing countries, will feel that they too will have to build up their own biotechnology research capacity in order to fulfill that function.

B. The "Privatization" of Research

1. The Surge of Private Agricultural Research

The rise of biotechnology has led to a sharp increase in agricultural research activity in private industry in the developed world as well as a shift of research resources from the public to the private sector. Worldwide spending on biotechnology-based R&D in all sectors including

pharmaceutical and chemical industries amounted to $4 billion in 1985 of which two thirds occurred in the private sector. Agricultural research accounted for $900 million of which $550 million was expended in the private and $350 million in the public sector (James and Persley, 1990, p. 371).

Two factors have been primarily responsible for this surge in private research activity. One is the political drive observed in many industrial countries to allocate a larger role to the private sector in areas that have traditionally been considered as government responsibility. This includes education, health care, and research. In particular, agricultural research used to be conducted primarily in public institutions and laboratories, associated with universities as in the United States, or directly sponsored by governments as in Europe. Changing policy perceptions have led to reduced funding of these activities from public sources.

Another factor which has boosted private research activity is economic opportunity, shaped by the strengthened protection of intellectual property in agriculture-related research. As discussed later in this paper, protection of new varieties and the appropriation of returns from inventive breeding activity became available in many countries only in the last several decades, while the possibility of protecting new life forms through patents was added through case law in the United States in the 1980s. Appropriability of the returns to research is seen by industry as a key condition for larger investment in R&D, and, in some industries, has proven to be a strong contributing factor (Evenson, 1990, p. 39).

For a while, this development suggested a new division of labor between public and private research in agriculture, with public systems emphasizing basic and strategic research, and industry attending to applied and adaptive research. However, with industry increasingly engaged in basic research, this distinction no longer holds.

The distinction has been further blurred by the increasing propensity of public researchers to seek protection for, and to control the commercial exploitation of, their inventions.

2. The "Privatization" of Public Research

Traditionally, the patent system's emphasis on monopoly and monetary gain has been seen as incompatible with the ethos of free availability of information in public research, particularly in areas of direct concern to human welfare such as medicine and food. Over the last fifty years, however, U.S. universities have debated the pros and cons of monetary gains to be derived, particularly from biology and biotechnology research. "Biology has been transformed, and so have the biologists. Virtually overnight, academic biologists never before involved with industry have become consultants, advisors, founders, equity holders, and contractors of new biotechnology firms or new divisions of multinational corporations. Patenting has become the norm in university biology departments" (Weiner, 1986, p. 42). Similar developments can be observed at European universities.

Concerns persist that discoveries originally funded from public moneys are patented and exploited by individuals; that resources are diverted from basic research to product development and management; and that the holding and commercial exploitation of patents, and perhaps even more the suing of patent infringers can only tarnish the reputation and credibility of a public research system and affect its continued access to public funds. "Despite all these problems, the prevailing mood in government, industry, and university biotechnology circles is to accept the new status quo" (Weiner, 1986, p. 43).

Most U.S. universities have set up intellectual property management offices or have engaged outside agencies such as Research Corporation of America to manage and defend their interests. As they have become sensitive to the value of their biological materials (e.g., biologically specific reagents, cell lines, or specific organisms), many

routinely place restrictions on the availability of these materials. These restrictions amount to a form of intellectual property protection by dint of contract and trade secrecy. Thus, there has been a change in the ways in which researchers and research institutions relate to one another.

3. Agricultural Research in Developing Countries

Developing countries generally underinvest in agricultural research, and most of it is conducted in the public sector (Evenson, 1990, pp. 36-38). Even seed multiplication is a public sector activity in many of them; the production of hybrid seed being a notable exception in some countries.[4]

The underfunding of agricultural research reflects the low priority generally given to research in developing countries; and the lack of an adequate research capacity and, in particular, of trained scientists and research staff. The lack of private sector research can be ascribed to the modest role allowed to that sector in many developing countries. The absence of some form of intellectual property protection may also have discouraged private R&D investment although developing country needs in this respect may differ from those of developed countries (Evenson, 1990, p. 46).

Developing countries are increasingly attempting to liberalize their economies and encourage a larger role by private initiative. Private adaptive research and breeding may develop. It will be helped by a growing interest of breeders from developed countries for whom developing countries are markets of increasing importance at a time when seed markets in developed countries are stagnant. These firms will need local partners for testing and

[4]"The concentration of private activity in the production of seed for hybrid varieties is explained by a natural phenomenon: The crop from a hybrid variety cannot be reused as seed (at least not without significant reduction in yield); this offers built-in intellectual property protection as long as the breeder guards the identity of or access to the parental lines used" (Lesser, 1990, p. 62).

multiplication. Similarly, as discussed later in this report, the international centers may encourage the establishment of a local breeding and seed industry in their client countries. As the introduction of plant variety protection may advance such a process, several developing countries are considering the introduction of protection.

C. The Changing Legal and Political Environment

1. Changes in National Laws in Industrial Countries

Intellectual property protection for plants and seeds has been steadily expanding over the last decades. Since the 1960s, plant varieties have been protected through plant breeders' rights in many industrial countries. With the more recent accessions of Australia, Canada, Hungary, Japan, and Poland, the membership of the International Convention for the Protection of New Varieties (UPOV Convention) has risen to twenty countries. A revision of the Convention has been negotiated in March 1991 (see Plant Variety Protection).

Concurrently, there is a tendency to extend regular patent protection to plants and plant material. This began in the United States with a 1985 Board of Patent Appeals decision that permitted plant varieties to be protected under the regular patent system. In Europe, which has not followed the U.S. example with respect to varieties, industry pressures are strong to do so and the European Communities have been working on a draft directive that would permit patenting of certain life forms. Several farm lobbies are opposing this proposal, while a desire to incorporate the results of other international negotiations currently underway is holding up its adoption.

The scope of currently available protection, and proposals under negotiation for its modification are discussed in the following paragraphs. Some details on protection available in individual countries and membership in international conventions are shown in Annex B.

a. Plant Variety Protection

Under "traditional" plant variety protection, also known as plant breeders' rights (PBR), available in the majority of developed countries and being considered in some developing countries, a variety can be protected if it is distinct, uniform, and stable. Protection generally implies that the owner of the variety can keep others from selling the variety commercially as seed. The farmer, however, can typically reuse a harvested crop as seed without violating the owner's rights.[5] A second important exemption permitted under the UPOV Convention allows use of the protected variety in a breeding program without permission of the owner.

Although these rights arise under national laws, the UPOV Convention sets internationally agreed upon standards for national laws. A diplomatic conference held in March 1991 revised that convention; the revisions will bind only those countries that ratify them. Among the changes agreed at the conference are provisions which make the farmers' right to reuse a harvested crop for new planting optional, that is subject to national law which need not grant the exemption. Another important change introduces the concept of the "essentially derived variety"[6] which cannot be produced or marketed without the consent of the original breeder. In the words of the

[5]In the United States, a farmer can also sell up to half of the crop as seed. These "brown-bag sales" have severely eroded the protection of wheat varieties.

[6]UPOV, Final Draft, International Convention for the Protection of New Varieties of Plants of December 2, 1961 as Revised at Geneva on November 10, 1972, on October 23, 1978, and on March 19, 1991 (Doc. DC/91/138). An "essentially derived variety" is defined as one that "(i) ...is predominantly derived from the initial variety ... while retaining the expression of the essential characteristics that result from the genotype ... of the initial variety, (ii) ... is clearly distinguishable from the original variety and (iii) except for the differences which result from the act of derivation, conforms to the initial variety in the expression of the essential characteristics that result from the genotype ... of the initial variety."

revised convention, "essentially derived varieties may be obtained for example by the selection of a natural or induced mutant, or of a somaclonal variant, the selection of a variant individual from plants of the initial variety, backcrossing, or transformation by genetic engineering." Consequently, a breeder who inserts a single new disease resistant gene into a variety protected by a plant breeders' right will have to obtain the original right holder's permission before marketing it.

b. Patent Protection for Plants

Over the last decade, some countries have been moving to also extend "regular" or utility patent protection to plants and plant components. As noted above, the United States has gone furthest in this direction. Europe has not followed the U.S. example; a provision in the European Patent Convention prohibits the granting of patents to "plant or animal varieties or essentially biological processes for the production of plants or animals." A provision in the UPOV Convention that prohibits the protection of "one and the same botanical genus or species" through both regular and PBR protection was modified in 1978 to permit some countries to join while retaining double protection systems — the modification facilitated U.S. accession to UPOV — and entirely dropped in the recent revision of the convention.

In addition, revisions to the basic global patent convention, the Paris Convention, which is the regular patent analogue of the UPOV Convention, were considered at a diplomatic conference in June 1991. Negotiations are to continue in 1992. There are two alternatives proposed for the "Fields of Technology" article of this convention. One alternative would follow the language of the European Patent Convention and exclude patents on "plant or animal varieties or essentially biological processes for the production of plants or animals," and would also permit countries to exclude certain types of technol-

ogy from being patented. The other alternative would require that patents be available for inventions in all fields of technology.[7]

c. Patenting of Varieties

In some patents obtained by U.S. plant breeding firms, specific varieties themselves have been protected under regular patent law.[8] Although the exact implications of such a patent have not yet been clarified in the courts, the patent may authorize its holder to restrict use of the patented plant for breeding purposes. It may also permit the holder to restrict farmers' reuse of the crop for new planting.

d. Patenting of Processes and Genes

The more innovative aspect of the new patent practice is its protection of novel processes that have been used in genetic engineering or of novel features that have been genetically engineered into an organism. It is being adopted at least in part by one developing country: Mexico changed its law in 1991 to allow patents on biotechnological processes for obtaining products such as pesticides but not on genetic material itself. Alternatively, in a number of countries, an innovator may patent a plant incorporating a gene taken from another species, claiming under the patent all plants of the host species (or of

[7]World Intellectual Property Organization (WIPO), "The 'Basic Proposal' for the Treaty and the Regulations," Diplomatic Conference for the Conclusion of a Treaty Supplementing the Paris Convention as Far as Patents are Concerned, PLT/DC/3, December 21, 1990.

[8]See, e.g., U.S. Patent 4,812,600 of March 4, 1989, issued to Stanley Jensen and Norman Williams and assigned to Pioneer Hi-Bred International, covering an inbred corn line. (There are many other such patents.) The abstract describes the patent as follows: "According to the invention, there is provided a novel inbred corn line, designated PHK29. This invention thus relates to the seed of inbred corn line PHK29, to the plants of inbred corn line PHK29, and to methods for producing a corn plant produced by crossing the inbred line PHK29 with itself or another corn line. This invention further relates to hybrid corn seeds and plants produced by crossing the inbred line PHK29 with another corn line."

species sufficiently similar that they could be transformed in essentially the same way) that incorporate the transferred gene. In essence, the innovator is protecting a "proprietary gene." The scope of the protection involved is unclear; it would certainly include the right to prohibit another firm from selling seed of the same host species containing the same (proprietary) gene, no matter how that gene had been acquired. In general, for the innovation to be adequately novel to meet patentability criteria, the gene involved has itself to be novel, i.e., not found in nature, or be transferred into a place in which it is not found in nature. It should not be possible to obtain a patent on a natural gene as found in its host or in other ways that it occurs in nature.

e. Constraints on Breeding Activity

The question of use of protected varieties in a breeding program is a point of special importance that is still unclear. The proposed European directive on biotechnological patenting provides for a (paid) compulsory license to permit certain uses of a protected variety as breeding material for another variety.[9] The current trend of international discussions, however, is to expand the use of protected material in a breeding program, coupled with strong rights to block marketing of the final breeding product if it comes within the scope of the initial patent. Under these circumstances, commercial incentives — rather than a formal compulsory license procedure — will normally lead to a negotiated license among the two breeders.

In addition, most countries' patent laws contain an experimental use exception that might allow for some use in a breeding program. In the United States, however, this experimental use exception is, in relevant contexts, defined by case law and not by statute, and is defined in a way likely to be restricted to academic use. Even though other countries use a broader exemption,

[9]Commission of the European Communities, Proposal for a Council Directive on the Legal Protection of Biotechnological Inventions (17 October 1988).

they may still limit it significantly, for example, by permitting experimentation on a patented invention but not experimentation with the patented invention for another purpose (presumably including improvement of the invention).

f. The Role of Trade Secrecy

Although the law is not changing very rapidly, the great importance of trade secrecy in biotechnology deserves to be noted. Trade secrecy is the form of intellectual property protection based on physical and contractual control over materials and information. Such information, if it "derives independent economic value . . . from not being generally known," and "is the subject of efforts that are reasonable under the circumstances to maintain its secrecy,"[10] is protected against theft in many nations — but not against copying based on materials and information that is publicly available. For example, the parental lines for hybrids or certain reagents or procedures used in genetic manipulation may be protected by trade secrecy rather than patent or plant variety protection. When other forms of intellectual property protection are unavailable, many firms will seek to protect their technology through trade secrecy.

2. The Uruguay Round and Trade Sanctions

The diplomatic conferences just discussed will lead, at most, to proposed modifications of existing conventions, and countries will be free to accept or reject those modifications. By contrast, current multilateral negotiations in the Uruguay Round if successful are likely to force all countries negotiating in this round, including developing countries, to protect intellectual property in the plant kingdom through either patents or plant breeders' rights.

The Uruguay Round of Multilateral Trade Negotiations, which began in September 1986 with the participation of some 108 countries, is intended to achieve

[10]Uniform Trade Secrets Act.

substantial liberalization of international trade as well as to set new global norms with respect to a number of areas not previously covered under the General Agreement on Tariffs and Trade (GATT), including agriculture, intellectual property, foreign investment regulations, and trade in services. It was to have been completed by the end of 1990, but negotiations stalled over the issue of reducing agricultural support in some industrial countries. Currently, new compromise arrangements are being discussed.

If the negotiations succeed, it is almost certain that they will include intellectual property provisions as part of a "package deal" which participants can only accept or decline in whole. Developing countries originally resisted negotiations of intellectual property issues in these negotiations but are likely to accept the new rules in return for improved access to developed country markets for such items as agricultural products and textiles.

These rules may include provisions requiring nations to protect trade secrets. Its biotechnology provisions are among the least agreed parts of what is otherwise a broadly agreed framework. The final code may require countries to provide for the protection of plant varieties by either patents or a *sui generis* system such as plant breeders' rights. This latter approach would reflect a compromise not only between the developed and the developing countries but also between the United States and the European Communities. The former would like any manmade invention including biotechnologically manipulated plants, to be patentable (save for inventions that violate the public order). The latter would prefer to permit plant variety protection and to deny patent protection to plant varieties and animals.

Finally, it should be noted that the United States has used trade sanctions to pressure other countries into strengthening their intellectual property systems. One interest served by the proposed international code is

to restrict such unilateral action and subject it to international review. Should the Uruguay Round agreement fail, unilateral trade retaliation would be likely to return.

3. Developing Country Positions

At this point, a number of developing countries have modified plant breeders' rights systems. None, however, has a system of the type urged by UPOV and none, to our knowledge, has granted regular patent protection on plants or seeds. Many developing countries explicitly exclude plants and seeds from patent protection (see Annex B).

Even in the absence of a Uruguay Round agreement — and *a fortiori* if there is such an agreement — this situation is likely to change substantially over the next decade. A large number of developing countries are considering adoption of a plant breeders' rights system; the UPOV secretariat anticipates a rapid increase in membership during the decade and points to at least six developing countries regarded as likely to join, regardless of the outcome of the Uruguay Round.

Thus developing countries appear to be dropping their traditional doubts about the validity of intellectual property protection. This move certainly reflects trade pressures, but also a recognition that the introduction of plant breeders' rights in the 1960s in advanced countries sparked an increase in private breeding activity. As indigenous industries are beginning to lobby for protection, some developing countries hope that such protection might similarly create or strengthen sorely needed private breeding and seed production capacity to supplement public sector activity, currently often underfunded or poorly managed, and that regular patents will encourage a biotechnology industry.

At the same time, developing countries are recognizing that the global moves toward biotechnology and toward intellectual property protection place increased value on their germplasm resources and are threatening

to restrict access to their germplasm, seeing it as a bargaining chip with which to gain increased funding and access to biotechnologies. This is the basis of the FAO Undertaking[11] and its 1989 Agreed Interpretations, defining Farmers Rights as a right to international funding in return for the germplasm developed by farmers over the centuries.[12] This claim is also at the base of recent proposals by countries grouped in the Southern Africa Development Coordinating Conference (SADCC) to withdraw from the Undertaking[13], by the U.N. Economic Commission for Latin America and the Caribbean to hold biodiversity resources as a "tradable good,"[14] and in the terms for access to genetic resources proposed in the current negotiation of a Biodiversity Convention. These claims will further blur the distinction — already difficult to maintain — between unimproved germplasm, for which a scientific free-flow regime should be the rule, and improved germplasm, for some of which an intellectual property-based commercial regime could be appropriate.

IV. MAJOR POLICY ISSUES FOR THE CENTERS

The preceding discussion has pointed to several trends and developments in the institutional and legal environment in which the international centers work. In response to these changes, some centers are adjusting the ways in which they structure their collaboration with advanced research institutions — both public and pri-

[11]Resolution 8/83 of the Twenty-Second Session of the FAO Conference, Rome, 5-23 November 1983.

[12]Resolution 5/89, Twenty-Fifth Session of the FAO Conference, Rome, 11-29 November 1989.

[13]Annual Progress Report, Sector of Agricultural Research and Training 1989-90, Submitted by the Government of Botswana, June 1990.

[14]"Biodiversity should be defined as a scarce resource and should consequently be assigned a price which reflects its opportunity cost in both spatial and temporal terms." United Nations, Economic Commission for Latin America and the Caribbean, 1991, *Sustainable Development: Changing Production Patterns, Social Equity and the Environment*, Santiago, p. 128.

vate — in developed countries. Will their other activities such as their cooperation with national programs be affected as well? And will other centers have to follow suit?

Of course the interests of individual centers differ, and we will review some of these differences in the section entitled "Special Issues for Individual Centers." However, four policy issues are common to all centers facing this changed environment. One is defining the areas in which it is possible to continue the traditional regime of free academic-style exchange. A second concerns the commercial exploitation of center inventions as a way to obtain revenues. A third reviews possible modifications in the centers' relations with their partner institutions in developing countries. And the last looks at how centers might structure their cooperation with private firms and advanced research institutions when accepting the intellectual property consequences in order to gain access to technology of potential benefit to developing world agriculture.

A. Issue One: Under What Circumstances Can the Current Open-Door Policy be Retained?

Where possible, and at least for part of their operations, centers will want to avoid the complications of proprietary rights protection. In keeping with traditional scientific procedures which envision a sequence of advances based on the ready exchange of research materials, information and ideas, centers would maintain their materials in the public domain, work with materials they can obtain without restrictions, and distribute their products without restrictions.

Under this scenario, centers would continue to publish their inventions. This puts an innovation in the public domain, and, generally, keeps others from appropriating and patenting. Due to ambiguities in U.S. law, publishing in the United States may not always suffice. For example, if a center finds an important gene with disease resistance and transfers it from a microbe

into a cultivar, it can, by publication, keep others from patenting that gene for use in that species. But unless the center did so first and published the fact, a firm that modified the gene might be able to patent the use of the modified gene in a number of species. And if the center identified the gene in a wild relative while the firm used genetic engineering techniques to transfer it to a primary cultivar, the firm might be able to patent its use even in the primary cultivar. In such situations — and there may be others like them — a center might seek patent coverage in order to protect its own access — and that of other centers and national programs — to the gene (and subsequent improvements made to that gene).

Even in the realm of advanced biotechnology, the increasing adoption of patenting practices need not, of itself, render a free exchange strategy obsolete as long as there are countries which do not protect such patents. The scope of patent protection is (almost) strictly territorial. In other words, if a gene has been patented in country A and not in country B, there is absolutely no illegality involved in using the gene in country B. The important implication is that scientists and breeders can work at ease in developing countries which do not provide intellectual property protection in the life form area; they do not need, in the first instance, to be concerned about the possibility that the materials they are working with are patented in developed countries. The most important exception — beyond that involved in maintaining good relations with developed world scientific collaborators — is that most countries are barring the import of products made with processes that would have violated a patent had the processes been conducted in the importing country. This will be an important issue for certain exports to industrial countries such as cut flowers; it will not be an issue for food commodities traded within or among developing countries not protecting such patent.

Discretion to deny intellectual property protection, or to offer only very limited protection, would, of course, be narrowed as a result of a successful Uruguay Round

of multilateral trade negotiations. In its wake, should host countries adopt intellectual property protection for plants and plant varieties, the risk will greatly increase that materials centers use are protected or that materials they develop will be used in protected varieties by others. At the minimum, this will require stepped-up vigilance on the part of the centers.

In determining when to maintain the free exchange/no-restrictions policy the centers ought to take into account the following aspects:

1. Points Opposing the Open-Door Policy

If centers pursue an open-door policy without compromise they are likely to find themselves losing access to leading technology. Increasingly, important technologies will be proprietary and will be made available to the centers only if the centers promise to respect the relevant proprietary rights in the materials supplied. Occasionally, proprietary rights holders will be willing to make their materials available for free use in a developing country while requiring a commitment to protect their developed country markets. However, with increasing globalization of seed markets and the growing importance of developing country markets, such unselfishness might wane.

Another concern of an open-door policy is that centers may forego the use of more effective conduits to bring their improved material to the farmers. In fact, as seed distribution in a number of developing countries is privatized, an effective way to bring a new variety to the farmer may well be through cooperation with private firms which, however, will regard proprietary varieties as more marketable than unprotected varieties (see Issue Three).

2. Points Favoring the Open-Door Policy

An open-door policy is, of course, least likely to create tensions with countries which supply germplasm,

however, they may hesitate to make their material available if they fear that others will secure proprietary rights on the material and profit from it. It may thus lessen the perils of loss of access to germplasm, a loss which would almost certainly slow increases in agricultural productivity and probably harm the developing world more than the developed world.

B. Issue Two: Income Generation from Patenting and Licensing

When should centers follow the example of a number of universities in industrial countries and seek royalties from their innovations? When should they, for example, take out intellectual property rights in developed countries and license these rights to firms in these countries while making their materials freely available within the developing world. This would ultimately provide additional resources for the centers which could be used to fund incremental research activity at the centers or at national programs. National agricultural research services could follow a similar course, by asking the centers to license or assign to them exclusive rights which they would commercially exploit or, in turn, franchise to private firms.

When assessing whether revenue generation is a worthwhile objective, one will have to keep the following aspects in mind:

1. Points Opposing Use of Patents for Income Generation

To the extent that new funding sources developed, donors might cut funding. Moreover, as has been a concern for universities in the United States that have adopted this strategy, research programs might shift toward market-oriented research at the expense of strategic research.

There are also questions with respect to exchange of materials and access to germplasm. A policy aimed at maximizing revenue from patenting would invariably

create incentives against sharing of germplasm between the centers and research institutions with which they collaborate. It would also reinforce the reluctance of developing countries holding unimproved germplasm to make that material available. Both the centers and the supplying countries would place restrictions on the commercial use of genetic materials supplied to other institutions. In the extreme, this could lead to a situation, where centers primarily supply relatively unimproved germplasm and, in essence, become paid conduits for the transfer of materials from developing to developed countries.

In this context, it should be noted that unimproved germplasm cannot be protected by patents because it is not novel. Screening and characterizing for traits does not change its quality as unimproved material and therefore does not render it patentable. Yet, some advanced research institutions in developed countries use their physical ownership of genetic materials for gaining returns from such material they hold. They will release it only against a commitment according to which a recipient agrees to share returns should the material, or any material derived from it, turn out to have commercial value.

We do not believe that centers should emulate this practice. However, in their relations with advanced research institutions and private industry that require commitments of the kind described, centers may wish to consider using unimproved screened and characterized material as a bargaining chip by equally insisting on a commitment that returns on commercial use of its germplasm be shared. In order to keep such negotiating options open a center would probably have to insist that recipients of its unimproved material routinely sign a material transfer agreement according to which the recipient cannot exploit the germplasm commercially without the prior consent of the center. It may also require this under its publicly announced germplasm distribution policy. Centers then have the discretion to waive such requirement for research institutions which do not

impose restrictions on the exchange of germplasm, and certainly with their traditional partner organizations in developing countries. When devising such policies, centers should remember that they hold these materials in trust and be mindful of the diplomacy that surrounded the 1989 FAO Undertaking on Plant Genetic Resources and led to the understanding that unimproved materials should be freely exchanged while improved materials could reasonably be subject to proprietary rights.

The situation may be viewed differently for material that has been improved through conventional breeding methods, or biotechnologically, and for which it can obtain protection. Particularly, when a center holds improved material which can be sold commercially in industrial country markets with little or no additional improvement, a center may want to license the germplasm against compensation. Such compensation should reflect the commercial value of the material to the buyer. It should, of course, not be sought if other arrangements can be worked out (e.g., exchange of material or provision of laboratory places for scientists from developing countries, to mention but a few).

2. Points Favoring Use of Patents for Income Generation

The advantage of this approach is that it would open a new source of funding for the centers. But how much will it bring in? If the experience of some major U.S. universities is a guide, returns from patenting would be modest. We understand that these universities expect to find one patentable invention for every $1 million to $2 million of research expenditure. In steady state, they net about one percent of their research budget from royalties after covering the cost of intellectual property management including litigation. To this should be added an amount — which seems to vary considerably from one university to another — of outright research grants that industry provides under cooperation agreements. In no case would it be realistic to conclude, however, that royalties will make a critical contribution to a re-

search budget, or significantly offset slumps in public funding.

C. Issue Three: Disseminating Innovation - The Centers' Relations with the National Programs

The advent of biotechnology is leading to a redistribution of roles played by the respective actors in the international research community: the centers, national programs, and industry in both developed and developing countries. As stated earlier, in developed countries, industry has staked out a prominent role in biotechnology research due to the fact that intellectual property law protects its inventions, allowing private industry to capture the returns; while limited public funding has constrained the entry of public research institutions into the biotechnology field.

In developing countries, similar changes are only beginning to occur. Government efforts to build an indigenous research capacity in the public sector have met with mixed success while private sector research is negligible. The entrance of the private sector into agricultural research will be a function of the anticipated market for biotechnology products, of existing agricultural research capabilities, and, most probably, of the availability of sufficient intellectual property protection. It could be sponsored by indigenous venture capital or foreign investors.

In most developing countries, the National Agricultural Research Systems (NARS) are currently the only conduit available to centers to adapt their research products and disseminate them to farmers. Yet, because of inadequate staffing and funding, the NARS have often turned out to be less than fully effective in discharging this role (Anderson, et al., 1988, pp. 110-119). The centers therefore have a strong interest in the emergence of a viable breeding activity in the private sector to share the tasks of national programs (Sawyer, 1990, p. 4). This would help farmers: they would obtain the benefits of improved varieties not only faster, but also would have

a broader choice of varieties. And as some argue, competition would also benefit the national programs;[15] it is, of course, equally important that public sector programs remain to deal with the needs of poorer farmers and to protect against the risks of monopoly.

Some developing countries have traditionally, or over a long time, followed a policy of controlling seed imports, exports, breeding and production. Often only the ministry of agriculture, or another public agency or enterprise, is authorized to engage in these activities. In other developing countries such policies are gradually being rescinded, as these countries are trying to assign a larger role to the private sector. In most of these countries — according to the memorandum of understanding under which a center conducts its programs in an individual developing country — the centers are limited in their collaboration to a public agency designated by the government. It would, therefore, be necessary to revisit such arrangements before a center can contract with private enterprises. Realizing that liberalization of the seed sector generally benefits the farmer and locally owned industry, and that foreign direct investment brings needed funding and technology, many developing country governments should be expected to be ready to ease restrictions on center operations and allow centers to collaborate with private enterprise, local as well as foreign.

As long as the centers or the NARS can avail themselves of only one conduit to disseminate a research product in a developing country, intellectual property protection is not relevant to their "downstream" relations in that country. It becomes relevant, however, once there is a choice among several conduits, coupled with the possibility to protect intellectual property. If, for instance, a center decides to disseminate an improved variety or

[15] "A less appreciated benefit is the salutary effect of the private sector on the public research institutions: they provide the competition the latter need to stir them from the complacency endemic to bureaucracies" (Javier, 1990, p. 419).

vaccine through a private firm (which may be the local branch of an international firm), the local firm, in order to effectively market and distribute the improved variety, may need the exclusive right to it. Otherwise the firm may not have the incentive to invest in advertising, distribution, and the extension activity that may go along with seed distribution. Should the center choose to disseminate through a national program, the national program may equally want exclusivity, or it may want to distribute through a private firm on the basis of an exclusive license. Notably, semi-autonomous public sector research institutions in some countries have approached centers for exclusive rights on materials developed by the center which these national institutions intend to commercialize in order to generate needed research funds. Though the decision to commercialize is made by a national program, the center's initial acquisition of intellectual property rights may be important in guarding the option for the national system to exercise the exclusive-rights choice.

It should be noted that what is typically important in marketing is exclusivity as recognized by the farmer. Thus, if the center is providing a finished variety, it can itself obtain variety protection and transfer rights to a national system or a private firm. If it is providing unfinished material, it can do so with exclusivity through a contract based on trade secrecy; alternatively, it can provide the material on a non-exclusive basis. In either case, a breeder working with the material might develop a finished variety protectable by a plant breeders' right.

1. Points Opposing Use of Proprietary Protection for Dissemination and Marketing

There is a risk of a negative perception if a center permits a private firm to make a profit on the product of publicly funded research. This will be less of a concern if the license it issues is non-exclusive, and available to all qualified parties without discrimination. If a center issues an exclusive license, it should do so on the basis of a competitive bidding process which is transparent

and from the outset lays down specific conditions and requirements.

Another concern must be the possible increase in the cost to farmers of the protected materials, and the attendant risk that a private breeder focus his marketing efforts on the well-to-do farmers because they can pay the higher price. It may therefore be necessary for a center, under a licensing agreement, to require assurances that the licensee will sell the protected material with only a reasonable markup for profit and/or continue making good public varieties available at competitive prices.

2. Points Favoring Use of Proprietary Protection for Dissemination and Marketing

In general, the private system is likely to offer the developing world farmer a wider choice than will be available through the public system. This is the reason why a number of developing countries, e.g. Mexico, are emphasizing the need to create a private seed supply sector. Moreover, pressures on public budgets in developing countries are such that the public seed supply sector and the National Agricultural Research Systems are likely to be inadequately funded; without reliance on the private sector, the centers' innovations may never reach the farmer.

D. Issue Four: Gaining Access to Patented Biotechnologies - How Should the Centers Structure Their Relations with Industry and Advanced Research Institutions in Industrialized Countries?

Centers need effective network relationships with universities and biotechnology firms in order to obtain patented technologies and adapt and advance them for the benefit of farmers in developing countries. These would, for example, include agreements under which a research laboratory inserts a proprietary gene into center materials for breeding and adaptation to developing country conditions. Contractual arrangements might specify the distribution of the product in such a way that

the resulting technology would be available within developing countries at a low or no charge, while the owner of the gene would protect its market in developed countries through patents or contractual commitments. In more complex arrangements, such as a joint research project, the firm and the center each supply particular technologies and each receives specific research products.

Examples of such network relationships have been established. Monsanto is providing its coat-protein virus technology to Mexico's Centro de Investigacion y de Estudios Avanzados (CINVESTAV) at Irapuato; several international centers have been in negotiations with Plant Genetic Systems of Belgium for *Bacillus thuringensis* genes.

Concerns a center should be aware of when entering into such arrangements are discussed in the following sections.

1. Points Opposing Network Arrangements with Private Firms

This approach may impact on the flow of genetic material within the CGIAR system. For example, a center may not be able to supply samples of a protected material (which might include any derivative material containing the proprietary gene) to a collaborator without first obtaining the permission of the patent holder. Even if transfer for research purposes is permitted, the recipient must be given warning that a variety containing the gene cannot be used without the patent holder's consent. Thus, any transfer of the material within the system, even to a "permissible" collaborator, would probably require special paperwork to ensure that the material was not passed further along inappropriately. While this kind of red tape may disrupt good scientific communication, it must be recognized that, in light of the restrictions that universities in industrial countries are imposing on the transfer of biological materials, not just patented materials, the CGIAR system will have to live with this form of control in any event.

What makes the transfer limitations even more serious is that it is now abundantly clear that they will restrict transfer *within* the developing world. There are several examples of firms allowing the free use of proprietary technologies in certain developing countries, and barring it in others, particularly in countries which are, or may become, attractive markets for them. Thus, a center may have to commit itself to deny certain countries access to certain germplasm. Whether these countries would still be able to use the material legally (after they obtain it from other sources) would depend on whether the material is patented in the country involved. Even without patents, however, the technology supplier may still condition the center's access to the technology on a commitment not to transfer the material outside certain countries or regions.

Further, it should be noted that the centers will have to face the vagaries of the patent battles. Currently, a number of firms are seeking patent rights to various strains of the *Bacillus thuringensis* gene. Some of the claims will undoubtedly overlap and be sorted out by the courts. There is a chance that a center may acquire a gene from a firm that turns out to be the loser in such litigation. The gravity of this risk is often lessened by the fact that the center can only be sued for patent infringement if a patent is in force in its host country or the host country of its collaborators. Moreover, this is a context in which center inventions might be useful bargaining chips in settlement negotiations.

2. Points Favoring Network Agrrangements with Private Firms

To maintain access to technologies and inventions which in the field of biotechnology will increasingly be generated in the private sector, and therefore more often than not be protected, centers will have to abide by the rules of the game under which intellectual property is traded. There will, however, be opportunities for forming alliances and networks with the private research sector in ways which will contain or even offset their cost. Often,

for instance, a firm will not want on its own to move its technology into a developing country, but would agree to cooperate with a center if it is compensated for incremental costs from such collaboration. This offers a way to make technologies such as the coat-protein virus technologies, the anti-sense technologies, and patented genes available to developing countries before the first round of patents expires sometime early in the 21st century.

V. SPECIAL ISSUES FOR INDIVIDUAL CENTERS

A. The Commodity Centers

For the commodity centers, a critical factor in determining their policy stance on intellectual property protection derives from the existence, or absence, of breeding activity for their mandated crop. The situation is clearly different for crops such as maize in which the private sector is conducting large-scale research, as contrasted with crops such as cassava for which there is essentially no private sector research. In the maize-type situation, the centers must be more concerned that they will accidentally infringe proprietary rights, and should expect that arrangements with the private sector will be marked by substantial restrictions on the flow of materials. Defensive patenting to obtain a bargaining position in negotiations with the private sector may be relatively more important — and it will be essential for a center to have precise information on what the private sector is doing. In the cassava-type situation, there is no need for such defense; the private sector will be more ready to provide innovations at incremental cost and flow restrictions associated with acquiring those technologies will be minimal. Generally, there is much less reason for concern with intellectual property issues.

The commodity centers must, of course, be sensitive to the evolutions of intellectual property protection in countries in which they or their collaborators operate, and to any consequent restrictions on the flow of material. As developing countries served by the centers adopt

stronger intellectual property protection, and become more important markets, the possibility for conflicts between centers and the private sector increases.

B. The Regional Centers[16]

In contrast, regional centers deal with a limited group of countries that will sometimes take a more homogenous position with respect to intellectual property. At the same time, they may face very different global patterns in the different crops that they deal with. Those regional centers whose mandated crops have a limited market in industrial countries can afford to ignore the intellectual property system, except to the extent they are forced to do so in the context of acquiring particular technologies. Those centers whose regions of responsibility include markets that appeal to firms will face much greater need to be aware of patent developments.

C. The Livestock Centers

The livestock centers will face issues associated with the global market for vaccines and veterinary products. Legal developments here have been different from those related to plants and seeds, mainly because there has been no tradition of an animal equivalent of plant breeders' rights, and the possibility of patenting animals has run well behind that of patenting plants. Nevertheless, vaccines and veterinary medicines have long been patentable in some countries, although others have resisted such coverage.

Another aspect peculiar to the livestock centers is that in order to bring their advanced vaccines to the market and the farmer, they frequently have no option but to co-opt high technology firms for the further development and marketing of the vaccine. Neither the

[16]We use this term as shorthand to refer to centers with an agroecological or a commodity orientation whose mandate is regionally limited, or had been so limited at the outset and subsequently extended.

center nor a national program would have the capacity to perform this task. As a result, a center will have no choice but to follow the intellectual property rules applying among research institutions and industry in this sector.

Because of the strength and importance of private sector distribution networks, and prevailing industry tradition, a center will likely have to agree on the distribution of its vaccine through an exclusive license under a patent which it will be expected to secure.

D. International Board for Plant Genetic Resources (IBPGR)

IBPGR faces the same issues as other centers. In addition, the global moves toward patenting pose special issues which IBPGR must face, either on its behalf or on behalf of the gene banks with which it works.

One set of questions concerns the need to ensure access to genetic resources in the face of the world's shift toward intellectual property. This is primarily a question of responding to moves by countries possessing genetic materials to make such materials no longer freely available. This is an issue of growing importance to which solutions must be found in a larger context which goes beyond the responsibilities of either IBPGR or the international centers system.

Another issue arises from the question of conserving "artificial" genetic materials, e.g. genetically engineered organisms, in gene banks. IBPGR should work with gene banks to define the circumstances in which such conservation is useful. Moreover, it must deal with the possibility that such material may be available only subject to transfer restrictions imposed by the original donor.

Finally, gene banks face the risk of providing genetic materials to users who will patent a portion of the genetic information contained in the materials. As indicated earlier in this paper, this risk is not as large as sometimes assumed. Patent law's conditions of novelty not being satisfied, a firm is unlikely to obtain a patent on a gene within its normal host range. More likely, the firm will take a gene from one species and patent its application in another species. Similarly, although it is conceivable that a plant might be taken directly from a gene bank and given plant breeders' rights protection, the more likely possibility is that the gene bank plant will be interbred with others before protection is obtained for a descendent. Even these situations may be politically embarrassing for a gene bank. Nevertheless, it must be noted that such use is in keeping with the purposes of a gene bank.

VI. CONCLUSIONS AND RECOMMENDATIONS

While problems and situations they confront differ, and the interests of individual centers vary, a reading of the situation leads to a number of conclusions that apply to all centers:

1. The trend within the international research community to protect intellectual property has advanced too far to be ignored by any CGIAR center. The centers will increasingly find that technology they need is subject to intellectual property protection and that an effective way to disseminate their innovations will be through private sector collaborators, often under exclusive rights. Moreover, as many developing countries are likely to adopt or strengthen intellectual property protection over the next several years, breeders will seek protection also in developing countries for advanced material of importance to their markets in both industrial and developing countries.

2. Much of the activity of the centers can continue without intellectual property protection

and without breaking with the centers' traditions of open scientific exchange. This will be particularly true for centers working in countries that have not extended intellectual property protection to plants and biotechnology and for centers whose mandate crops have little commercial interest for industrial country markets.

3. Under current policy, centers should not restrict the flow and release of *unimproved* germplasm including germplasm which has been screened and characterized. They may wish to consider changing to a policy of safeguarding their bargaining position by requesting a material transfer agreement to be routinely signed by institutions that will not reciprocate a center's free exchange policy. In contrast, centers may consider licensing their *improved* germplasm to *breeders and producers who intend to market it* in industrial countries with little or no additional breeding.

4. Only rarely will intellectual property protection and commercialization in industrial countries be a lucrative option for centers. However, centers scoring research advances in areas of high commercial interest should consider acquisition of patents in industrial countries, not so much as defense against seeing their innovations appropriated by third parties (that is better done through publication), but as bargaining chips to maintain access to proprietary technologies. There might be cases in which a center should patent an exceptionally important invention as a source of income, but these would be rare.

5. As it will be imperative for the centers to continually gain access to new proprietary technologies of potential use to developing countries, they will require understanding of patents and licensing; acceptance of commercial materials subject to restricted use will also entail acceptance of

restrictions on the free intersystem exchange of materials.

6. Finally, each center should carefully review the institutional linkages by which its innovations reach the farmer and should protect its innovations when such protection is likely to help in marketing the innovations to developing country farmers.

In order to help the centers in defining and executing such policies, we recommend that:

1. The CGIAR should establish a set of intellectual property policies and guidelines, within which individual centers would define their own rules and procedures. Such a Policy Statement should *lay down the ground rules to which the centers* will adhere when structuring their "upstream" relations with technology providers and research collaborators. It might also sketch out the new partnerships centers are looking for in their "downstream" relations with breeders and the seed industry in developing countries. The Policy Statement should consistently reflect the position the Group and its centers take on related issues (e.g., on genetic conservation and biodiversity) and should therefore also serve to contain the risk that expanding intellectual property protection will eventually slow the flow of germplasm.

2. Individual centers should draw up their own rules and procedures to provide for:

i. germplasm distribution;

ii. standard networking arrangements likely to be needed to bring in outside technologies and — to the extent reasonably predictable — the kinds of proprietary re-

strictions that may be accepted, and of center innovations they would consider patenting; and

iii. in-house procedures for controlling proprietary information, employee agreements, relationships with patent counsel, periodic reviews of intellectual property changes in host and other countries, and reviews of intellectual property trends affecting their mandate crops.

3. At least in an initial phase, and until centers have built up sufficient capacity to manage their intellectual property, they should consider the creation of a central facility to provide basic advice and to refer centers to legal counsel appropriate to their specific concerns. Such a facility should also allow centers and their staffs in charge of intellectual property management to exchange information and experiences on patent and plant variety matters. During the start-up of this new activity, centers should arrange, perhaps with the help of other international agencies and intellectual property groups, workshops to help their scientists, their staffs working on intellectual property issues, and their colleagues from national programs to understand the basic concepts as well as the costs and benefits associated with intellectual property, and to ensure that the technical aspects of the law not hinder their mission.

ANNEX A

IN-HOUSE POLICIES AND PROCEDURES FOR INTELLECTUAL PROPERTY MANAGEMENT

Should a center decide to embark on a significant intellectual property program, it will need to consider a variety of administrative steps.

A. Intellectual Property Management

1. Network Arrangements

Assuming the central issue for moving into intellectual property management is the acquisition of useful proprietary technologies, a center will need the supporting legal capability to negotiate these agreements. It may want to develop specific guidelines as to the kinds of exclusivity that it will accept, or it may consider the hard choices on a case-by-case basis. It will also need the legal support to structure the agreement, taking into account both local intellectual property law as well as the laws of countries in which protection and collaboration could be important. And in cases in which there are known patent disputes, the center may want to have a patent firm do a careful evaluation of the strength of the technology supplier's intellectual property position.

2. Tracking Procedures

The center will also have to develop procedures for proprietary information and material among its own research staff. These will include at least: a logging system, employee agreements committing them not to pass on information or material that should be retained by the center, and standard forms and procedures for gaining commitments from third parties to whom material is provided. If a center is going to develop its own proprietary information, primarily to direct dissemination,

similar procedures will be necessary for protecting that information. In particular, the center will want to use a standard material transfer agreement.

3. Patent Application and Litigation Processes

If the center is going to pursue its own patent applications, it will need to set up appropriate procedures. This will typically involve a local patent specialist who regularly works with the center and a network of relations with patent searchers and patent attorneys in countries in which patents are regularly filed. There should be a careful review of the importance of the innovation before expending funds for patenting. Perhaps most important — and possibly controversial — will be the internal network to ensure that inventions are brought to a patent specialist to be reviewed for possible patenting.

A center would normally turn to specialized firms for litigation. Such litigation is expensive and should be rare, but sometimes may have to be considered to maintain the centers' credibility if the effort spent obtaining patents is not to be wasted or if inventions are not to be placed unfairly in the private domain by others.

4. Cost of Intellectual Property Management

To estimate the cost of intellectual property management, both initially and in steady state, is not possible. Some ball park numbers may, however, be of interest.

The cost of obtaining a typical patent, including search, filing, and attorneys' fees, is on the order of $9,000 to $14,000 in the United States;[1] it may be somewhat less in other countries. The average cost of patent litigation in the United States is about $0.5 million (on each side) per claim litigated and will probably be less in other legal systems.

[1]These are 1988 numbers (rounded) from R. Foltz and T. Penn, *Protecting Scientific Ideas and Inventions* (Penn Institute, 1988, p. 142).

B. Staff Policies

1. Employee Agreements

If a center is going to protect material of its own, there will have to be an employee invention agreement, defining relative rights of employees and the center in innovations. It should also govern the employee's use of materials that may be proprietary to a technology supplier. The details will typically depend on local law. The centers may also want to create their own reward procedures for employee innovations.

2. Information Procedures

In addition to the procedures noted above to protect proprietary information supplied by others, the center will need to have a variety of information-control mechanisms if it is going to pursue its own patent coverage. This includes laboratory notebooks, a pre-publication review procedure for scientific manuscripts (to ensure that patents are filed before publication), and possibly control over the transfer of biological materials in order to ensure that the center is able to obtain patent coverage when it desires, and to protect its position in the event of patent litigation.

C. Collaboration Within the CGIAR System

It may be desirable for the centers to cooperate on certain of these activities. For example, it would be valuable for them to exchange data on patent firms they find best in particular jurisdictions. Similarly, there is no need for centers to duplicate one another in evaluating the intellectual property position of a particular firm offering a specific gene. And, should there be a substantial number of innovations arising from the centers, the CGIAR might usefully operate a common licensing operation. Some kind of a facility serving all centers, at least during an initial period until they have built up in-house capacity to manage their intellectual property, should be considered.

ANNEX B: OVERVIEW OF PATENT PROTECTION (1988)

Country	Memberships			Length of Patent Protection Under National Legislation	Patent Protection on Plants and Plant Product 1: Food Products 2: Plant/ Animal Varieties 3: Microorganisms and Products Thereof		
	Paris	Berne	UPOV		1	2	3
LOW INCOME							
Bangladesh				16c,d	■	■	■
Benin	■	■		10a,d	■		■
Burkina Faso	■	■		10a	■		■
Burundi	■			20a	■	■	■
Central African Republic	■	■		10a,d	■		■
Chad	■	■		20a	■	■	■
China	■			15a			■
Gambia, The				20a	■	■	■
Ghana	■			20a	■		■
Guinea	■	■		e	■	■	■
Guinea-Bissau	■			e	■	■	■
Haiti	■			5,10,20c	■	■	■
India		■		14b		■	■
Indonesia	■			e	■	■	■
Kenya	■		‡	20a	■		■
Lesotho				20a	■	■	■
Liberia				e	■	■	■
Madagascar	■	■		e	■	■	■
Malawi	■			16b,d	■	■	■
Mali	■	■		10a,d	■		■
Mauritania	■	■		10a,d	■		■
Niger	■	■		10a,d	■		■
Nigeria	■			20a	■		■
Pakistan		■		16c,d	■	■	■
Rwanda	■	■		20a	■	■	■
Sierra Leone				20a	■	■	■
Sri Lanka	■	■		15c	■		■
Sudan	■			20a	■	■	■
Togo	■	■		10a,d	■		■

Country	Memberships			Length of Patent Protection Under National Legislation	Patent Protection on Plants and Plant Product 1: Food Products 2: Plant/ Animal Varieties 3: Microorganisms and Products Thereof		
	Paris	Berne	UPOV		1	2	3
Uganda	■			20a	■		■
Tanzania, U. Rep. of	■			20a	■		■
Viet Nam	■			15a		■	■
Zaire	■	■		20a	■	■	■
Zambia	■			16b	■	■	■
LOWER-MIDDLE INCOME							
Bolivia				15c		■	■
Botswana				20a	■	■	■
Brazil	■	■		15a	■	■	
Cameroon	■	■		10a	■		■
Chile		■	¶	e	■	■	■
Colombia		■		5c,d	■		■
Congo	■	■		10a,d	■		■
Côte d'Ivoire	■	■		10a,d	■	■	■
Dominican Republic	■			5,10,15c	■	■	■
Ecuador				5c,d			■
Egypt	■	■		15a,d		■	■
Jordan	■			16a	■	■	■
Lebanon	■	■		15a	■	■	■
Malaysia				15c	■		
Mauritius	■			14a,d	■	■	■
Mexico	■	■		14c	■		■
Morocco	■	■		20a	■	■	■
Peru		■		5c,d			■
Philippines	■	■		17c	■	■	■
Poland	■	■	■	15a			■
Senegal	■	■		10a,d	■		■
Swaziland				20a	■	■	■
Syria	■			15a	■	■	■
Thailand		■		15a			■
Tunisia	■	■		5,10,15,20a		■	■
Turkey	■	■		5,10,15a	■	■	■
Zimbabwe	■	■		20a	■	■	■

Country	Memberships			Length of Patent Protection Under National Legislation	Patent Protection on Plants and Plant Product 1: Food Products 2: Plant/ Animal Varieties 3: Microorganisms and Products Thereof		
	Paris	Berne	UPOV		1	2	3
UPPER-MIDDLE INCOME							
Algeria	■			20a	■		■
Argentina	■		¶	5,10,15c	■	■	■
Barbados	■	■		15a,d	■		■
Gabon	■	■		10a,d	■		■
Greece	■	■		15a	■	■	■
Hungary	■	■	■	20a		■	
Iran	■			5,10,15,20a	■	■	■
Iraq	■			15a	■	■	■
Korea, Republic of	■			12b		■	■
Libya	■	■		15a,d		■	■
Malta	■	■		14a,d	■	■	■
Portugal	■	■		15c			■
Romania	■	■		15a			
Seychelles				20a	■	■	■
South Africa	■	■	■	20a	■		■
Suriname	■	■		e	■	■	■
Taiwan (China)				15c			
Trinidad & Tobago	■	■		14c	■	■	■
Uruguay	■	■		15c	■	■	■
Venezuela		■		5,10c		■	■
Yugoslavia	■	■		7b,d			
HIGH INCOME							
Austria	■	■		18b	■		■
Australia	■	■	■	16b,d	■	■	■
Bahamas	■	■		16a	■		■
Belgium	■	■	■	20a	■		■
Canada	■	■	■	17c	■		■
Cyprus	■	■		20a	■		■
Denmark	■	■	■	20a	*		■
Finland	■	■		20a			■
France	■	■	■	20a	■		■

Country	Memberships			Length of Patent Protection Under National Legislation	Patent Protection on Plants and Plant Product 1: Food Products 2: Plant/ Animal Varieties 3: Microorganisms and Products Thereof		
	Paris	Berne	UPOV		1	2	3
Germany	■	■	■	20a	■		■
Iceland	■	■		15c		■	■
Ireland	■	■	■	16b,d	■	■	■
Israel	■	■	■	20a	■		■
Italy	■	■	■	20a	■	§	■
Japan	■	■	■	15b	■	■	■
Liechtenstein	■	■		20a	■		■
Luxembourg	■	■		20a	■		■
Netherlands	■	■	■	20a	■		■
New Zealand	■	■	■	16b	■	■	■
Norway	■	■		20a			■
Spain	■	■	■	20a	■		†
Sweden	■	■	■	20a	■		■
Switzerland	■	■	■	20a	■		■
United Kingdom	■	■	■	20a	■		■
United States	■	■	■	17c,d	■	■	■
UNCLASSIFIED							
Bulgaria	■	■		15a			■
Cuba	■			10a,d			■
Czechoslovakia	■	■		15a		■	
Korea, Dem. Ppl's Rep.	■			15a	■	■	■
Mongolia	■			15a		■	■
U.S.S.R	■			15a	■		■

SOURCES: WIPO (1988), Gadbaw and Richards (1988). Ranking according to World Bank national income data.

NOTES: *a* from filing date; *b* from publication date; *c* from grant date; *d* extension possible—typically 5 years; *e* no information available; ■ denotes membership; ¶ grants PBRs, but not member of UPOV; * processes patented under some circumstances; § Italy allows plant varieties but not animal varieties; † excluded until 1992; ‡ PBRs not yet implemented.

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