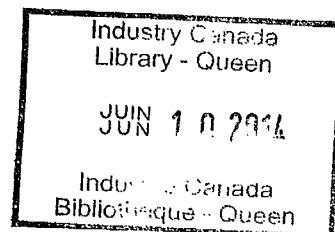


**THE BIODIVERSITY CONVENTION,
INTELLECTUAL PROPERTY RIGHTS,
AND OWNERSHIP OF GENETIC RESOURCES:
INTERNATIONAL DEVELOPMENTS**

**PREPARED FOR:
INTELLECTUAL PROPERTY POLICY DIRECTORATE
INDUSTRY CANADA**

JANUARY, 1996



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INTERNATIONAL DEVELOPMENTS

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**THE BIODIVERSITY CONVENTION,
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EXECUTIVE SUMMARY

1.0 Introduction

The 1992 Convention on Biological Diversity has brought to the foreground the question of the relationship between conservation of biological diversity, sustainable use of its components, which include genetic resources, and the issue of the "fair and equitable sharing of the benefits arising out of the utilization of genetic resources." (Article 1, "Objectives".)

Scientific advances, especially in areas of biotechnology research, have focused the attention of the scientific and industrial world on biodiverse genetic resources. And at the same time, the benefits arising out of their use are now recognized as potentially substantial. In particular, intellectual property rights are sought and frequently obtained in the intangible information obtained or derived from unique genetic material from such resources. Negotiations leading up to the Biodiversity Convention raised the question of using intellectual property rights as part of the "sharing of the benefits" arising out of the utilization of the genetic resources.

This study examines the provisions of the Biodiversity Convention and the parallel discussions within the Food and Agriculture Organization of the United Nations (the FAO), relating to these questions. It outlines some of the approaches being proposed and considered within identified international organizations and certain resource-rich (primarily, developing) countries, on issues of access to genetic resources, both in terms of the tangible resource itself and to the intangible information contained within the genetic material of the resource; ownership and use of the tangible and intangible property in the genetic resources; and how these issues are being addressed -- for example, through access agreements, prior informed consent mechanisms, and material transfer agreements.

This is a companion study to a literature review conducted on the same issues ("Intellectual Property Rights, Biotechnology and the Protection of Biodiversity: Literature Review," by Howard Mann). That paper develops the issues addressed here in a conceptual and analytic framework, reviewing the ideas presented on each issue in the literature. By contrast, this paper reports on developments relating to these issues, in the identified organizations and countries.

2.0 Analysis of the Biodiversity Convention: Biotechnology and Intellectual Property Rights

The Convention on Biological Diversity created significant controversy with the inclusion of provisions that concerned biotechnology and intellectual property rights. The American refusal to sign the Convention until the last minute, and its continued non-ratification, both supported and fuelled this controversy. Increasingly, however, the view that the Convention does not through its own terms change international or national law as it relates to intellectual property and the transfer of technology has become a consensus view. This includes the view that the Convention does not alter on any laws outside of the Convention dealing with the patenting of life forms.

The Convention does, however, clearly signal new directions and relationships or developments in this area. Perhaps the most significant change was the articulation of the common concern principle in place of the common heritage principle as the underpinning for sovereign control over genetic resources and as the foundation for the control of access to these resources. This change has been supported by the inclusion of the access to genetic resources provisions in the Convention, based on a regime of prior informed consent and mutually agreed terms. It is this control over access that provides resource-owning states the ability to gain equitable compensation for their use in the development of new products.

The prior informed consent regime also allows the state of origin to seek access to technologies, products or knowledge as part of the mutually agreed terms for allowing access. This could include technologies and products subject to intellectual property rights, but any adjustments to these rights would also, under the Convention, be subject to mutually agreed terms with the holder of those rights.

Implementation of this aspect of the Convention through national legislation has become a growing focus of developing countries, as is seen in the country studies that follow. Such legislation will generally set out both procedural and substantive conditions for an access regime to be entered into by the state in question. While this does not directly deprive a holder of IPRs of these rights, they can (in theory) impose limits that many rights holders will not find acceptable, and thereby limit access to resources in this way. The Convention requires, however, that states party ensure conditions that are favourable to access and the sustainable use of genetic resources.

A major new direction signalled by the Convention is the recognition of the role of indigenous peoples, their knowledge and their practices in the conservation and sustainable use of genetic resources. This has raised significant questions concerning the protection of indigenous knowledge and practices through some form of intellectual property right or system, as well as the goal of ensuring appropriate rewards for the use of such knowledge by others in developing products and processes. Many questions on the compatibility of existing IP regimes with the protection of indigenous knowledge and practices are raised by these goals. The Convention signals the need to address them, but does not pre-determine the outcome of this consideration.

Current activities in this area within the Convention structures are geared to ensuring a full information base is achieved prior to any international negotiations to further the implementation of these aspects of the Convention. Preliminary studies done up to the second Conference of the Parties in November, 1995, will be augmented over the coming months, prior to the third such meeting. In the meantime, a more coordinated relationship with other organizations dealing with related issues will be developed, most importantly the World Trade Organization.

3.0 The FAO and the Global System for the Conservation and Utilization of Plant Genetic Resources for Food and Agriculture

The FAO, which has had responsibility for global conservation of plant genetic resources for food and agriculture, continues to serve as the primary forum to address issues of access to plant genetic resources, especially those *ex situ* collections that existed prior to the adoption of the Biodiversity Convention, and the issue of Farmer's Rights. This study reviews the regime established by the FAO concerning conservation of and access to these resources, and proposals for revision of this regime.

Since 1983, all the activities of the FAO have been in furtherance of its Global System for the Conservation and Utilization of Plant Genetic Resources, intended to promote conservation and sustainable use of plant genetic resources through international cooperation. The study reviews the various elements of the Global System, of which the most important for present purposes are the 1983 Undertaking, the Commission on Plant Genetic Resources ("CPGR", a permanent intergovernmental forum on plant genetic resources), and the International Code of Conduct for Plant Germplasm Collecting and Transfer.

The 1983 International Undertaking on Plant Genetic Resources, which for ten years was the only international agreement governing terms of access to plant genetic resources for food and agriculture, was based on "the universally accepted principle that plant genetic resources are a heritage of mankind and consequently should be available without restriction." (Article 1) This unrestricted access was qualified, however, by other provisions in the Undertaking that set out alternative ways in which samples of genetic resources could be made available: free of charge, on the basis of mutual exchange, or on mutually agreed terms.

The "free access" provisions of the Undertaking were then further limited by three resolutions, adopted after 1983 and attached as annexes to the Undertaking, which sought to balance concerns expressed by developed and developing countries by providing for both plant breeders' rights and farmers' rights.

In November, 1993, the FAO adopted a Code of Conduct for Plant Germplasm Collecting and Transfer, a voluntary code that establishes minimal standards for the issuance of permits and licences for the collection of plant germplasm. Based on the "common concern of mankind" and "national sovereignty" principles, rather than the "common heritage" one, the Code encourages states to establish systems for the issuance of permits to collectors, sets standards of conduct for the

collectors (to protect the resources), and asks users to consider providing some form of compensation to local communities, farmers and the source country, on mutually agreed terms.

The FAO is currently engaged in revising the 1983 Undertaking, in accordance with the Biodiversity Convention, and for the realization of Farmers' Rights. Studies prepared in anticipation of these discussions, recognize that plant genetic resources for food and agriculture may require fundamentally different solutions from other genetic resources, to ensure their conservation, development and availability, and the fair and equitable sharing of benefits derived from their use. Their history, geographic location, and the great inter-dependence among nations for these resources, combine to create a unique problem that must be addressed on its own terms.

The legal status of the *ex situ* collections of plant germplasm remains unsettled. The study outlines the possible interpretations of the applicable regime, and options being considered to govern access to the germplasm in such collections. Since 1990, the International Agricultural Research Centres (IARCs) have taken the position that they are not the owners of the germplasm in their collections, but that they hold them in trust on behalf of beneficiaries, who have been variously identified as humanity, developing nations, the farming communities, and research workers. The Centres take the position that the material stored is to be made available without restrictions, and that no intellectual property rights are to be sought over such material. Material transfer agreements are to be used to prevent third parties subsequently claiming intellectual property rights in the material.

A recent meeting of the CPGR Working Group studying these issues was unable to reach a consensus on how the 1983 Undertaking should treat material stored in germplasm collections, in particular material acquired before and after the entry into force of the Biodiversity Convention. This material could be viewed as outside the Convention, and freely available as part of the heritage of mankind; or, as still outside the Convention, but with the host country able to legislate on ownership and conditions of access; or, as subject to the country of origin of the resource, so that the permission of the country of origin is required for the release of genetic resources from pre-existing collections. Difficulties of identifying the country of origin have been highlighted.

The issue of Farmers' Rights has been of central importance, particularly as plant breeders' rights are strengthened worldwide through agreements such as the TRIPs chapter of the Uruguay Round. Continued attention is being given to implementing these rights; the issues to be addressed are described in detail in this study.

4.0 Survey of Comparative Approaches to the IPR/Biodiversity Linkages

A number of interesting initiatives are underway in the countries surveyed. Several of these initiatives -- notably those in the Andean Pact countries, the Philippines, The Gambia and Cameroon -- were cited in a recent report by the Secretariat to the Conference of the Parties to the Convention on Biological Diversity (Biodiversity Convention Secretariat Report, 1995), and may therefore be influential in the development of other national, and perhaps multilateral, policies and legislation governing access to genetic resources.

The **Andean Pact** countries (Bolivia, Colombia, Ecuador, Peru and Venezuela) have been working on a Common Regime on Access to Biogenetic Resources, that would reflect the implement the Biodiversity Convention. The draft decision prepared to effect this common regime starts from the premise that states have sovereign rights over their natural resources, and the authority to determine questions of access to those resources. All states would declare all genetic resources to be part of the national patrimony.

All access to genetic resources, for scientific, commercial or industrial purposes, is to be regulated by the member-states on the basis of prior informed consent and mutually agreed terms. The source country is a mandatory party to any decision on access, even where the requested access is to a resource on private property.

The draft decision adopts the concept of Farmers' Rights, and the vesting of those rights in the international community as trustee.

The proposals leading up to preparation of the draft decision recommended making access to genetic resources subject to governmental authorization, which would consist either of a valid Certificate of Origin (for *in situ* resources), or a Material Transfer Agreement (for *ex situ* resources). Every subsequent transfer of the accessed material would have to be accompanied by this authorization. This system would link the access requirements and intellectual property regimes: patents and other intellectual property rights would only be granted upon presentation of the Certificate as proof of prior informed consent.

The draft decision also recognizes rights of indigenous and local communities over their knowledge, innovations and practices. The issue of the extent to which such rights should be recognized, was contentious during the development of the draft decision. One of the proposals leading up to preparation of the draft decision recommended extending intellectual property rights (not just tangible property rights) to biodiverse genetic resources whose value resided in the fact of their conservation, rather than in any novelty.

Special conditions are to be established for access to genetic resources of indigenous and local communities, to enable these communities to secure compensation. The draft requires that those seeking access to indigenous knowledge, innovations and practices must conclude an agreement directly with the indigenous peoples, as a condition precedent to granting rights of access to associated genetic resources.

The **Costa Rican** experience has had perhaps the most influence internationally of any single country. The strategy employed was multi-faceted, involving: the establishment of a large National System of Conservation Areas; the creation of a National Institute of Biodiversity (INBio -- Instituto Nacional de Biodiversidad) to conduct an inventory of the country's natural resources, and to work with national and international institutions towards appropriate economic and intellectual use of those resources; establishment of a strong legal framework regulating access to and control of biological samples; and implementation of social policies to create a skilled and educated workforce.

The study reviews each of these aspects of the Costa Rican strategy, with particular focus on the legal framework and the terms of INBio's access agreements with commercial and research organizations, seeking access to Costa Rican genetic resources. Under the *Wildlife Conservation Law*, the State has the exclusive right to commercialization of genetic resources, which are declared to be part of the national patrimony. INBio is authorized by the government to enter into its access agreements, while a significant portion of revenues received under the agreements is transferred to the government for conservation purposes.

The standard INBio access (or bioprospecting) contract includes terms for up-front payments, as well as royalty payments; technology transfer; and regulation of the ownership of both the tangible resource specimens, and the intangible rights in the information in or obtained from the specimen. These contracts have laid the framework for virtually all subsequent bioprospecting agreements, wherever located and whomever between.

Mexico recently established CONABIO, the National Commission for the Knowledge and Use of Biodiversity. CONABIO's role is primarily one of promotion and coordination; it does not itself engage in the collection of specimens (unlike INBio). It is in the process of developing a policy framework to govern access to Mexico's genetic resources. It recently prepared draft bilateral agreements with Australia, Cuba, Costa Rica and the United States, for cooperative activities in developing, accessing, analyzing, managing and communicating biological data information.

Cameroon recently established a legislative framework for integrated management, conservation and sustainable use of forests, fauna and fisheries. The legislation provides that genetic resources belong to the state, and prohibits anyone exploiting the resources for scientific, commercial or cultural purposes, without authorization. The law also requires payment of royalties to the state, where financial or economic benefits result from the use of Cameroonian genetic resources.

A study was recently conducted of the regulatory context in Cameroon governing bioprospecting, and recommendations were made for improvement. This study, and the recommendations, are detailed in this survey.

The Gambia recently enacted legislation authorizing the competent national authority to regulate, including prohibiting, trade or traffic in any component of biological diversity. The genetic resources are declared to be an essential part of the natural wealth of resources of the people The Gambia. The implementing regulations and guidelines are to regulate the export of germplasm, the sharing of benefits derived from Gambian germplasm, and fees for access to the germplasm.

In **India**, there is currently no single, coordinated legislative framework governing access to and use of genetic resources. A proposal for a system of regulation of access to genetic resources is in the preliminary stages of preparation, but no legislation has been introduced and the substance of the proposal remains confidential. This study reviews the controversial (related) amendments to Indian intellectual property laws, and also a proposal by the Third World Network for an alternative intellectual property regime to protect indigenous and local communities' knowledge and resources.

The Philippines recently issued an Executive Order prescribing guidelines for scientific and commercial bioprospecting. The Order reiterates Philippine constitutional law that wildlife, including flora and fauna, are owned by the State, which has full control and supervision over its disposition, development and utilization. It establishes an Inter-Agency Committee on Biological Resources, which would include representatives of different government departments, academics, non-governmental organization representatives, and representatives of indigenous communities and organizations. This Committee would consider bioprospecting applications, and review the Philippine legislative framework. (Among other things, the Committee is specifically directed to consider new laws on intellectual property rights.)

All bioprospecting of biological and genetic resources must be pursuant to a Research Agreement concluded with the government. This can be either a Commercial Research Agreement or an Academic Research Agreement. The Order stipulates minimum terms for these agreements, and these are detailed in the study. Among others, the terms must regulate the quantity of specimens that may be removed, and require continued access for Philippine government entities and citizens to both those tangible specimens and to the intangible data, where the specimens are removed from the country. Provision must be made for the payment of royalties, if commercial use is derived from the resource, and possibly other forms of compensation provided as well.

Notably, the Order requires the prior informed consent of local and indigenous communities, before bioprospecting will be permitted on "ancestral lands and domains" of these communities. The Order is explicit that royalty payments must be made to these communities.

In **Indonesia**, the current regulation of access to genetic resources is found in the Rules and Procedures Governing Permission from the Government of Indonesia for Foreign Researchers to Conduct Research in Indonesia, issued by the Indonesian Institute of Science (the so-called "LIPI Rules"). While these remain officially in effect (and their terms are detailed in this survey), in fact we are advised that access is usually determined under the terms of access agreements, for example concluded with universities or the United States National Cancer Institute (NCI). These terms are also discussed in this study.

Australia is in a highly unusual position, as both a supplier and user of genetic resources. This perspective presents an opportunity for Australia to play a lead role in shaping international practice.

Responsibility for environmental matters is divided among the Commonwealth, States and Territories. Much of the policy, legislative and administrative framework for the management of living and non-living resources, falls within State and Territorial authority. The study reviews the existing legislation in the States and Territories regulating access to Australian genetic resources. For example, the Queensland government is in the process of preparing draft legislation vesting ownership of the genetic material of Queensland wildlife in the state, and regulating access through a permit system, with financial agreements regarding the use of genetic materials.

Australia is currently considering using a Commonwealth-State consultative process to arrive at a national approach for managing access to Australian genetic resources, but this process is not expected to be completed before early 1996.

There have been several studies of appropriate ways to regulate access to Australian genetic resources, and these are described in detail. The studies note the need to consider the use and ownership of the traditional knowledge, innovations and practices of indigenous and local communities, including benefit sharing mechanisms, and the issue of the ownership of flora and fauna on indigenous peoples' lands and the use of appropriate intellectual property mechanisms. One study recommended the establishment of property rights that relate to the development and sale of genetic products, and establish intellectual property rights derived from knowledge of genetic diversity, especially of indigenous peoples.

One report recommended the adoption of three basic principles to protect Australian interests as a biodiverse nation: (1) that Australia control access to indigenous biological resources in accordance with the terms of the Biodiversity Convention; (2) that international access be granted on terms that recognize Australia's rights of ownership in the genetic material, rights to involvement in research on the material, and rights to fair and equitable return on, and proportionate ownership of, commercial products developed from Australian biological resources; and (3) that the governments reserve the right to set fees, royalties or other charges relating to the grant of access, and to receive all reports of research relating to the commercial potential of those resources.

In **New Zealand**, the issue of the role of intellectual property rights in establishing terms of access to or use of genetic resources, is still in the early stages of discussion. The Government placed a moratorium on the issuance of permits to collect genetic material for commercial purposes, and is in the process of identifying stakeholders to assist in preparation of a new policy on the issue.

A major issue in New Zealand has concerned the cultural and intellectual property of indigenous peoples, particularly with respect to traditional knowledge of the Māori. Recent developments on this issue, including the 1993 Mataatua Declaration, the Treaty of Waitangi claim of Māori ownership of indigenous flora and fauna, and proposed amendments to New Zealand intellectual property legislation, are detailed below. For example, the Treaty of Waitangi claim, scheduled for pre-judicial hearing later this year, will address Māori claims that the New Zealand government breached the Treaty by allowing the patenting of inventions, and the granting of plant breeders' rights (called plant variety rights), in relation to indigenous flora.

Finally, a series of **regional roundtables** were organized in 1994, bringing together leading individuals in the field from government, non-governmental organizations, indigenous peoples' groups, regional institutions, international institutions, and the scientific and academic communities. The ideas presented and discussed at these roundtables are discussed below.

5.0 Survey of International Activities

Activities at the international level surrounding the issues of intellectual property rights, biotechnology and biodiversity appear to be increasing in number and scope. This includes both inter-governmental organizations and non-governmental ones.

The World Trade Organization has become the critical inter-governmental organization, besides the Biodiversity Convention framework, concerned with these issues. The WTO Committee on Trade and Environment considered the relationship between the WTO and the Convention in June, 1995, and will do so again in April, 1996. The initial discussion was general in nature, reflecting the positions and views that had developed in the Convention context and the negotiations on the TRIPS Agreement. The second discussion is expected to define the central areas of concern that the WTO members believe require further consideration or study. In May, 1996, the Committee will determine whether this area is one to be brought forward to Ministers at the WTO Ministerial meeting in December, 1996.

Of primary interest is the treatment of the patenting of life forms in TRIPS, and the requirement for patent protection to be available for all technologies, without discrimination. Restrictions in TRIPS on the compulsory licensing of technologies is also an area of interest for many states. The relationship of the two agreements in the event of a dispute that might involve them both is also considered an important element, especially by environmental groups.

The World Intellectual Property Organization (WIPO) has not, to date, played a significant role in this area. This does not appear likely to change in the near future, despite their role as the "guardian" of international intellectual property agreements.

The United Nations Human Rights Commission, Working Group on Indigenous Peoples, has assumed a high profile role in this area, focussing on the issue of indigenous intellectual and cultural property. While not related expressly to the Biodiversity Convention, this Working Group has produced documents that will impact on developments in the Convention context. Most notably, they have espoused a dynamic and wide ranging view of what should be considered as the rights of indigenous peoples in this area, as well as a strong procedural position on the need to ensure the active involvement of indigenous representatives in any process that seeks to address these issues. A Draft Declaration on the Rights of Indigenous Peoples has now begun its negotiating phase under this Working Group, and includes significant references to the issues raised by the Convention.

The OECD is seeking to develop a stronger appreciation of the responses to the Convention that its members have made, or could bring forward. A survey of members will provide the background material for an OECD meeting to be held early in 1996 in Australia. This meeting is not designed to develop a single response strategy.

The non-governmental response from environmental groups (ENGOS) has focussed on two issues, and their linking: the local conservation and sustainable use of genetic resources and the role and rights of indigenous peoples. Linking these two issues has provided both significant institutional

developments and contacts among previously diverse groups, as well as a powerful rights-based approach to many issues.

Ensuring an equitable sharing of benefits for the use of genetic resources, and the necessary transfer of technologies, is seen as critical to providing the full economic value for local conservation efforts. This, in turn, will ensure they can continue to be made. Many ENGOS have reluctantly come to accept that the economic interaction necessary to do this will require some recognition of intellectual property rights over resulting new products. The approach in this regard has become, increasingly, one of providing the assistance needed to ensure that mutually agreed terms of access lead to an equitable sharing of the benefits flowing from these rights.

Finally, it is noted that business groups have not been as active in this area as in other international agreements in the form of international associations. Still, many businesses and institutions continue to show leadership in the development of bilateral agreements that implement, in different ways, the intent and objectives of the Convention in the absence of implementing legislation that requires this. In addition, several private sector codes of conduct for the harvesting of genetic resources have been developed to guide professional activity in this area.

ACRONYMS USED THROUGHOUT THE STUDY

Consultative Group for International Agricultural Research	CGIAR
Commission on Plant Genetic Resources	CPGR
Food and Agriculture Organization of the United Nations	FAO
General Agreement on Tariffs and Trade	GATT
International Agricultural Research Centres	IARCs
International Board for Plant Genetic Research	IBPRG
International Plant Genetic Resources Institute	IPGRI
Intellectual Property Policy Directorate	IPPD
Intellectual Property Rights	IPRs
International Union for the Conservation of Nature	IUCN
African Intellectual Property Organization	OAPI
Organization for Economic Cooperation and Development	OECD
Prior Informed Consent	PIC
Swedish Agency for Research Cooperation with Developing Countries	SAREC
Scientific and Technical Advisory Body (FAO)	STAG
United Nations Conference on Environment and Development	UNCED
United Nations Environment Program	UNEP
International Union for the Protection of New Varieties of Plants	UPOV
Trade-Related Intellectual Property Rights	TRIPs
World Intellectual Property Organization	WIPO
World Trade Organization	WTO

**THE BIODIVERSITY CONVENTION,
INTELLECTUAL PROPERTY RIGHTS, AND
OWNERSHIP OF GENETIC RESOURCES:**

INTERNATIONAL DEVELOPMENTS¹

1.0 INTRODUCTION

1.1 Background to the Review of International Developments

The 1970s gave birth to two radically different, yet oddly complementary, phenomena: ecological consciousness and biotechnology. Today, the international community faces the difficult challenge of reconciling them.

Ecological consciousness has taught us that we live in a world in which a myriad of disparate factors have conspired to destroy many of the natural resources we once took for granted. Pollution, over harvesting, agricultural specialization, overpopulation, soil erosion, deforestation and urban sprawl, to name a few, have been stripping many industrialized, or "developed" nations of all but a relatively few natural resources. At the same time, an abundance of diverse biological resources still exists, primarily in the southern "developing" nations. These resources are now recognized for their contribution both to a healthy global environment, and to the biotechnology industries of the north.

The techniques of biotechnology offer hope of regenerating a poisoned and depleted environment, producing crops able to grow and thrive in diverse soils and circumstances, and curing disease. At the same time, to a world that still carries the shadows of DDT, DES, thalidomide and other chemicals, these optimistic predictions are greeted by many with hope tempered by a degree of scepticism, fear and determined caution.

¹ I would like to thank the numerous people who gave so generously of their time and knowledge to provide information and assistance with this study, including: Howard Mann, who also contributed sections of this report; Geoff Oliver, Adrienne Blanchard and Lucie Guibault of Industry Canada; Dr. Brad Fraleigh and Carole Martin of Agriculture Canada; Chusa Gines, Danna Leaman and their colleagues at IDRC; Professor William Lesser; Dr. José-Luis Solleiro (Mexico); Brendan Tobin (Peru); David Hathaway (Brazil); Dr. Sujata Arroya (India); Dr. Carlos Correa (Argentina); Dr. José Esquinas-Alcázar (FAO); Sean Goddard (New Zealand); Rod Holesgrove (Australia); Dr. Rodrigo Gómez and Dr. Ana Sittenfeld (Costa Rica); Dr. Setijati D. Satrapradja (Indonesia); Deborah Hurley (OECD); Jeff McNeely (IUCN); Susan Bragdon and Angela Cropper (Biodiversity Convention Secretariat); Adrian Otten, Richard Eglin, and Harsha Singh (WTO); Ricardo Sateler (WIPO); Barry Greengrass (UPOV); and all the officials within the Government of Canada who took the time to review and comment upon the first draft of this report. The insight and information provided by each of these individuals was invaluable. Of course, all errors are solely attributable to the authors.

The confluence of ecological consciousness and biotechnology brings new opportunities for the developing nations, whose resources now can be valued more appropriately than occurred in the past. Moreover, this is occurring at a time when international trade is collapsing barriers throughout the globe, imposing universal standards of legal protection in the interest of creating a "level playing field" and opening economic opportunities. Some of the most contentious of the "universal standards" being imported concern protection of intellectual property for biotechnology inventions. These have created acrimonious confrontations between some developed nations and some developing ones; at the same time, the new-found opportunities for the genetic resources of the developing nations provide the latter with a new perspective and strength in bargaining, that may significantly alter the politics of the debate.

Just as biotechnology has shattered the conventional limits of human endeavour, so the new awareness of the value of biodiverse genetic resources has opened up debate on a myriad of heretofore unquestioned premises: should the natural resources of the world be freely available to all, as was the norm for many years? Or, as was decided in the negotiations of the 1992 Convention on Biological Diversity, should they be the property of the nation where they are located? Are the genetic resources we see flourishing in developing nations properly viewed as the products of nature, or the result of generations of communities' conservation and breeding?

Traditionally, intellectual property rights did not attach to new varieties of plants; only in the 1960s did a movement begin to recognize the value of plant breeding, and create a compensable right in the new plant that was created. Now, the limits of the debate are being pushed further, as suggestions are raised that intellectual property rights (not only physical property rights) be created to recognize and compensate the contribution effected within the local communities that has resulted in the present day richness of genetic resources.

The purpose of this paper is to outline some of the approaches being proposed and considered to address these issues. The focus here is primarily on developments within certain international organizations and certain resource-rich nations. A similar study is currently underway by the OECD on the developed nations, and separate studies are planned by Industry Canada focusing specifically on Canadian needs and concerns. All the resource-rich nations chosen for this study -- with the exceptions of Australia and New Zealand -- are developing nations, and the views, concerns and perspectives reported in this study reflect this fact. The purpose of this study was to report ideas and developments in the identified regions, without trying to identify "preferred" policy directions or choices. Any imbalance in the views discussed is due to the focus on resource-rich nations, and does not reflect a recommendation by the authors of this study that the reported views should or should not be adopted or followed.

Because of the breadth of the issues, the limited time available, and the difficulties (even in this technologically advanced age) of collecting information from literally around the globe, this is not an exhaustive survey of current developments in the regions. Hopefully it will, nevertheless, provide some insight into how these issues are presently being addressed, and current thinking in the countries concerned as to how they should be addressed.

This is a companion study to a literature review conducted on the same issues. While attempts have been made to minimize overlap, some duplication is inevitable. This study focuses on reporting developments and ideas in and about particular regions -- what may be described as the "fact-finding" aspect of the project; the literature review considers and analyses the ideas themselves in greater depth, and for their global implications -- what may be termed the "idea-finding" aspect of the review. The authors' intention and hope was that the two studies would be read together.

The objective of both studies is to lay a foundation for the later development of policy approaches and positions for the Canadian government. This matter is plainly one of international magnitude. It is therefore appropriate for Canada, in developing its policy, to take account of developments in the key countries relevant to the issues.

1.2 Methodology

The methodology adopted for this study was as follows:

- (a) The pertinent texts and literature relating to the Biodiversity Convention were identified and analyzed. These included the text of the Convention, and statements of negotiators and states on adoption, ratification and signature, as well as secondary literature. Documents relating to the work of the Conference of the Parties since the Convention was signed were also examined.
- (b) Key Canadian government officials were contacted for knowledge and suggestions on international contacts and events. As noted above, the parameters of this study focus on international organizations, and certain particular countries and regions. The Canadian experience, needs and concerns were not part of this review, and will be considered separately in other studies by the Canadian Government.
- (c) A list of countries was prepared for the review of country activities, and appropriate contact points identified. Relevant international, including regional, organizations and appropriate contact points were identified.
- (d) A questionnaire (a copy of which is attached as Appendix A) was prepared and sent to the country, regional and international contact points concerning:
 - the existing arrangements under which biotech research and development are currently proceeding (eg, terms of access, terms of technology transfer, ownership of intellectual property rights);
 - the degree of satisfaction with existing arrangements; and
 - government or other initiatives to implement or apply the Biodiversity Convention, or to revise existing practice with respect to issues of concern, either in legislation or other policy directives.

- (e) Contacts were also asked to provide references to source documents related to developments in their country and region.

In the result, we found that the questionnaire was more useful as an avenue of focusing subsequent discussions with the individuals contacted, than in producing answers to the specific questions posed in the questionnaire. In most cases, individuals chose not to reply to the questions specifically, but instead to provide source materials and information on developments in their country, region or organization. This material, and the discussions with the respondents, was extremely useful, and in the result was the source of much of the information reported below.

- (f) Officials at the Biodiversity Convention Office, WIPO (and UPOV), the WTO, and governmental and non-governmental organizations were contacted and interviewed during meetings in Ottawa, London and Geneva. Government officials in the countries selected for the national review were contacted and interviewed by telephone. All interviews were conducted on a "background only, off-the-record" basis. The information obtained has been incorporated into this report, but without specific attribution, in order to ensure a full and frank discussion.
- (g) Primary and secondary source material was obtained and reviewed with respect to the issues under study, both with respect to the identified countries and with respect to international and regional organizations.
- (h) Throughout, attempts were made to coordinate the work with other agencies undertaking related studies, in particular the Biodiversity Convention Secretariat and the OECD, and other work commissioned by the Intellectual Property Policy Directorate ("IPPD") of Industry Canada.

The research for this study was concluded in June, 1995. Selected later developments within the FAO, the Biodiversity Convention Secretariat and the Conference of the Parties have been incorporated into this paper.

1.3 Analytical Framework

The Biodiversity Convention lays the groundwork for national, as well as international, linkages between the conservation of biological diversity, the sustainable use of the components of biological diversity, and the "fair and equitable sharing of the benefits arising out of the utilization of genetic resources." [Article 1, "Objectives," of the Biodiversity Convention.] Several contextual or thematic points may assist in providing a framework for the analysis of the various approaches and ideas among the international organizations and the countries and regions surveyed, to give effect to these linkages.

The first fundamental distinction is between control over the *tangible samples* of genetic resources -- the physical specimens -- and control over the *intangible information* contained in unique genetic material obtained or derived from those samples. With respect to the physical, tangible samples, there is a further distinction: they may be located *in situ*, that is, in the natural habitat of the particular resource; or they may be located *ex situ*, defined in the Biodiversity Convention to mean outside the resource's natural habitat. *Ex situ* resources include those housed in genebanks.

The issue of control over the *intangible information* contained within the genetic material, and the control over the application and modification of this information, raises the issue of *intellectual property rights*, which can grant or restrict rights of *ownership* and *use* (including subsequent applications and modifications) of unique genetic material.

The *access* issue is fundamental to both. *Physical access* to the tangible specimens is, as will be seen, increasingly subject to control by the national government with respect to its *in situ* resources; genebanks are also grappling with the question whether to continue to grant unrestricted access to their germplasm, or whether they (or the nation from which the specimen was obtained) should impose some restrictions on access. This marks (and reflects) a shift in approach, from the position that genetic resources were part of the "common heritage" of mankind and therefore freely accessible to all, to the position that each state has sovereign rights over the genetic resources found within its territory, and can control the rights of access to those resources. The Biodiversity Convention is explicit that access to genetic resources requires the *prior informed consent* of the state where the resources are located. Increasingly, states are exercising this right of control through *access agreements*, whose terms also seek to regulate the ownership and control of, as well as the access to, the *intangible* information, as well. Genebanks similarly are using *material transfer agreements* to regulate subsequent private claims in intangible information in genetic resources obtained from their *ex situ* collections of germplasm.

Recent proposals for *legislative* approaches to these issues include requiring proof of prior informed consent or a valid material transfer agreement, before affording recognition of patent rights.

This leads to another theme which underscores this study: what may be termed the "cooperative/competitive dynamic" within the international community around these issues. The globalization of commerce, the fact that genetic resources are usually found *in situ* in more than one jurisdiction, and the fact that, with extensive germplasm collections housed in genebanks throughout the world, many resources can be obtained from a variety of sources, all combine to place added emphasis on the need for multinationally accepted resolutions to these issues. Changes to intellectual property regimes in one jurisdiction would have limited effect; however, as ideas are adopted in several states, they can be extremely effective. As will be seen, models that have worked well in Central America have been studied for adoption in Africa and Asia. These trends toward international cooperation will be highlighted throughout this study.

There is a potentially "competitive" edge to this "cooperative" dynamic, which has been noted in the literature, but so far does not appear to have threatened relations among states. This emerges out of the identical factors noted above: insofar as genetic resources are available from more than one source, or conversely desired by more than one company, the potential exists for competitive bargaining of the terms of access to the resource (as well as the potential for monopolistic control of resources through exclusivity arrangements).

Finally, note should be made of an important consideration in determining terms of access to genetic resources, namely that with scientific advances, very small quantities of tangible material may be required for chemical or genetic analysis, after which it may be possible to reproduce the active ingredient either chemically or even through bioengineering of another organism. Thus increasingly, restricted terms of continued physical access may be less important than the terms related to the subsequent use and control of the intangible information.

These are some of the major issues and themes that underlie current approaches to the issue of the linkages between conserving biological diversity and protecting intellectual property rights.

This study is divided into six parts. Section 2.0 outlines the history of events leading up to the Biodiversity Convention of 1992, and then analyzes the provisions of that Convention, with emphasis on those that relate to the themes identified here.

Certain plant genetic resources for food and agriculture and issues relating to these resources fall outside the Biodiversity Convention, and are addressed under the auspices of the Food and Agriculture Organization of the United Nations ("FAO"). Section 3.0 reviews recent developments within the FAO for addressing access to and rights in these genetic resources, particularly in light of the issues of concern that have emerged out of the Biodiversity Convention.

Thus these two sections (2.0 and 3.0) set out the basic international framework in which these issues are being addressed. The next part (section 4.0) surveys developments in the identified countries and regions. In each case, there is first a general section that provides some basic background on the geographic area, followed by a section on the current ideas, approaches and activities reported for that country or region.

Section 5.0 reviews recent activities of international organizations on these issues, looking at both intergovernmental and non-governmental organizations. Finally, section 6.0 sets out brief conclusions, returning to the themes of this framework.

2.0 ANALYSIS OF THE BIODIVERSITY CONVENTION: BIOTECHNOLOGY AND INTELLECTUAL PROPERTY RIGHTS (IPRs)²

Summary:

The Convention on Biological Diversity created significant controversy with the inclusion of provisions that concerned biotechnology and intellectual property rights. The American refusal to sign the Convention until the last minute, and its continued non-ratification, both supported and fuelled this controversy. Increasingly, however, the view that the Convention does not through its own terms change international or national law as it relates to intellectual property and the transfer of technology has become a consensus view. This includes the view that the Convention does not alter on any laws outside of the Convention dealing with the patenting of life forms.

The Convention does, however, clearly signal new directions and relationships or developments in this area. Perhaps the most significant change was the articulation of the common concern principle in place of the common heritage principle as the underpinning for sovereign control over genetic resources and as the foundation for the control of access to these resources. This change has been supported by the inclusion of the access to genetic resources provisions in the Convention, based on a regime of prior informed consent and mutually agreed terms. It is this control over access that provides resource-owning states the ability to gain equitable compensation for their use in the development of new products.

The prior informed consent regime also allows the state of origin to seek access to technologies, products or knowledge as part of the mutually agreed terms for allowing access. This could include technologies and products subject to intellectual property rights, but any adjustments to these rights would also, under the Convention, be subject to mutually agreed terms with the holder of those rights.

Implementation of this aspect of the Convention through national legislation has become a growing focus of developing countries, as is seen in the country studies that follow. Such legislation will generally set out both procedural and substantive conditions for an access regime to be entered into by the state in question. While this does not directly deprive a holder of IPRs of these rights, they can (in theory) impose limits that many rights holders will not find acceptable, and thereby limit access to resources in this way. The Convention requires, however, that states party ensure conditions that are favourable to access and the sustainable use of genetic resources.

² Sections 2.1 - 2.4 were contributed by Howard Mann, whose assistance with this study is gratefully acknowledged.

A major new direction signalled by the Convention is the recognition of the role of indigenous peoples, their knowledge and their practices in the conservation and sustainable use of genetic resources. This has raised significant questions concerning the protection of indigenous knowledge and practices through some form of intellectual property right or system, as well as the goal of ensuring appropriate rewards for the use of such knowledge by others in developing products and processes. Many questions on the compatibility of existing IP regimes with the protection of indigenous knowledge and practices are raised by these goals. The Convention signals the need to address them, but does not pre-determine the outcome of this consideration.

Current activities in this area within the Convention structures are geared to ensuring a full information base is achieved prior to any international negotiations to further the implementation of these aspects of the Convention. Preliminary studies done up to the second Conference of the Parties in November, 1995, will be augmented over the coming months, prior to the third such meeting. In the meantime, a more coordinated relationship with other organizations dealing with related issues will be developed, most importantly the World Trade Organization.

2.1 History and General Scope of the Biodiversity Convention

While the negotiation of the Convention on Biological Diversity formally took place from February 1991-May, 1992, its evolution pre-dates this brief period. Early reflections of interest in creating a global biodiversity conservation treaty are found, for example, in the United Nation's 1982 World Charter for Nature.³ Spurred on primarily by the International Union for the Conservation of Nature, this Charter placed a greater focus on flora and fauna issues than had, for example, been seen in the 1972 Stockholm Declaration on the Human Environment.⁴

Following the successful adoption in the UN of the World Charter for Nature, the IUCN continued its push for a binding legal instrument that would take a broad, integrated perspective on biological diversity conservation. Common arrangements to this period had focussed on species-specific concerns, in particular endangered and migratory species, the protection of specific, internationally important natural heritage sites, and the protection of special ecosystems, such as wetlands of regional or international importance. The legal efforts of the IUCN and others were bolstered in the mid-1980s by the rapidly increasing appreciation of the rate of loss of flora and fauna, and the potential consequences of this loss.

Both the NGO initiative and the growing public awareness led the United Nations Environment Programme (UNEP), in 1987, to recognize officially the need to review this fragmented approach to biological diversity conservation. It created a Working Group to review the current legal framework, suggest means to rationalize it, and consider the possibility of an umbrella agreement to address this and other issues. This Group completed its work in 1990, and

³ *International Legal Materials*, Vol. 22, p. 455, 1983.

⁴ *International Legal Materials*, Vol. 11, p. 1416, 1972.

concluded there was a need for a new international agreement on biodiversity conservation. The Working Group continued on to produce a document with draft elements of a possible biodiversity convention, which was subsequently modified by the UNEP Secretariat to become a draft treaty text for purposes of negotiating the convention. This latter text was presented when the negotiations began in 1991, under the auspices of UNEP.⁵

The original intent of the IUCN, environmental groups and developed countries in supporting the initiation of negotiations was the establishment of a broadly framed conservation agreement. By the time the negotiations actually began, however, the broader UNCED process was in full swing, and the demands from the South for a significantly broader conception and appreciation of environment and development had taken firm roots. Thus, the first session of the negotiations revealed the full scope of issues that would eventually become reflected in the final text of the Convention, adopted on May 22, 1992, in Nairobi. This included, primarily, issues related to the economic development of the South, and the financial and technological support of this development by the North. In short, the convention negotiations went from being conservation-focussed to a combination of biodiversity conservation and biodiversity use, the latter creating direct links to the biotechnology issues, concerns and expectations of the South. (Sánchez, 1994; Chandler, 1983; IUCN, 1994)

The full scope of issues found in the Convention is reflected in Article 1, "Objectives":

The Objectives of this Convention, to be pursued in accordance with its relevant provisions, are the conservation of biological diversity, the sustainable use of its components and the fair and equitable sharing of the benefits arising out of the utilization of genetic resources, including by appropriate access to genetic resources and by appropriate transfer of relevant technologies, taking into account all rights over those resources and to technologies, and by appropriate funding.

The text that follows this article includes elements relating to conservation of biological resources, the sustainable use of the resources, access to and transfer of technologies, and other financial mechanisms to support the objectives of the Convention in the biodiversity-rich countries of the South.

The conservation obligations under the Convention apply to *in situ* resources as well as *ex situ* resources. They include provisions on the development of proper national biodiversity management plans, assessment and inventories of biodiversity, environmental impact assessment from a biodiversity perspective, the identification and monitoring of biodiversity, the establishment of protected areas, rehabilitation of degraded ecosystems, promotion of the recovery of threatened species, development or maintenance of legislation for endangered species and cooperation at the international level to achieve the aims of the Convention.

⁵ This historical précis is adapted, *inter alia*, from IUCN, 1994, and Burhenne Guilmin & Casey-Lefkowitz, 1993.

The integration of sustainable use and conservation objectives into national decision-making is a further obligation, as is the development of incentives for the sustainable use of biodiversity. Fair access to the resources for all contracting parties is also included. Related to this is the series of obligations on training and research, public education and awareness, exchange of information and technical and scientific cooperation in support of both the conservation and sustainable use of biodiversity. A financial mechanism is established for assisting developing country parties in achieving the objectives of the Convention, and other institutional mechanisms for the proper operation of the Convention, including a scientific body, secretariat and conference of the parties are created. A clearinghouse mechanism for technology cooperation is foreseen, but not yet operational.

One result of the firm link, throughout the UNCED process, of environmental protection and conservation to economic development, is that the provisions on technology transfer are intimately bound up with both the sustainable use and conservation goals. Biotechnology is expressly included as one aspect of technology in the Convention, and is made the focus of several provisions on access to technology in the context of technological cooperation, technology transfer and as part of the sharing of benefits for providing access to genetic resources.⁶

2.2 The provisions concerning intellectual property rights

In addition to the negotiations in the Biodiversity forum, two other sets of related multilateral negotiations were taking place at the same time. One was in the GATT Uruguay Round, which included negotiations on the trade related aspects of intellectual property rights. The other was specifically on plant genetic resources, and was conducted in both UPOV (International Union for the Protection of New Varieties of Plants) and the FAO (United Nations Food and Agricultural Organization). All of these negotiations had the common link of dealing with intellectual property protection of life forms and the transnational respect for such rights and related technologies. The GATT also dealt with intellectual property rights in the more general trade context. This section reviews the results of the negotiations on these issues in the Biodiversity Convention. Although just one aspect of the complex relationship of many of the provisions of the Convention, it is this one aspect that constitutes the subject matter of this review.

Some context is important here. Prior to the negotiation of the Biodiversity Convention, biological resources had often been conceived of as part of the common heritage of mankind, with free access for all. This conceptualization, which lasted right into the 1980s, included access to traditionally cultivated and developed crops, as well as plants naturally occurring in nature. However, during the 1980s and the first years of the 1990s, developing countries began to see access to genetic resources modified by technological processes (biotechnology) as becoming increasingly

⁶ Articles 2, 16(1).

restricted due to an expansion in the number and scope of patent claims by biotechnology companies in the North.⁷

These circumstances led to the view that the biodiversity rich South was providing genetic resources free to the North, which was then selling back products developed from these resources subject to exclusive patent rights.⁸ The perceived inequity led developing countries to try to reverse this situation. Two tracks for doing so were developed in the negotiations. The first was the recognition of national sovereignty over the resources, and a consequential shift from common heritage to the common concern doctrine. The second was the limitation on patent rights over life forms by the biotechnology industry, as well as over other technologies relevant to the biotechnology sector and the conservation of biodiversity. The first objective was accomplished. The second, it is suggested below, was not, though it must be acknowledged that some controversy remains on this point.

One final contextual point. The negotiations on the IPR related provisions were among the most divisive and difficult of the entire Convention. This has been clearly reflected in some of the convoluted language and the high number of cross-references in the key articles. It is also clear, as will be seen below, that scope for different approaches to implementation of some of the provisions has been left to the parties, as is the case with virtually all the obligations in the Convention. It will be suggested below, however, that these factors do not preclude a responsible, objective interpretation of the Convention.

2.2.1 Intellectual property rights on life forms

The text of the Biodiversity Convention makes it clear that it did not purport to decide the question of the legal and ethical validity under international law of patents on life-forms. Such patents, as already noted, have increased in volume and scope over the past two decades, and now cover genetically engineered animals, crops and drugs, as well as related biotechnological processes. Literally thousands of patent claims remain to be adjudicated in the US alone. The Paris Convention, which regulates international patent law, has not been seen to prohibit such patents, and, under the national laws that provide the basis of all patent protection, US, European and other countries have shown an increased acceptance of this practice.⁹

Despite the efforts of the developing countries to seek a ban on such patents, and the contrary efforts to seek an express reference to their legality by some developed countries, the Convention effectively leaves the law outside the Convention on this issue unaffected. It neither requires patents

⁷ For a general description of developments in this area see, eg., Reid et. al., 1993.

⁸ This situation is reported on in many reviews of the Convention. See, eg. IUCN, 1994, introduction; Caillaux, 1994, p. 12.

⁹ This is noted in most commentaries on the patent issues. See, eg. Reid et. al., 1993, pp. 18-24.

on life forms from those countries that do not provide for them, nor rejects them from those that do. This is seen in two ways. First is the absence of any special mention of the issue directly. Second is the definitional notation that technology includes biotechnology, combined with the references to respect for patents on all technologies, without any exclusion for life forms or associated processes. This result has been lamented by advocates for both sides in the debate, but not controverted as the result of the negotiation.¹⁰

Reflecting the growing divisions of the South on the patent issue following the ratification of the GATT Uruguay Round, and the coming into force of the Biodiversity Convention, at least some authors from the South have now suggested that they should recognize the new situation and "play the game" by seeking to establish patent or *sui generis* rights that are more reflective of the type of practices and technologies that prevail in the South in relation to the conservation and development of genetic resources. (Caillaux, 1994, p. 13) The sections below indicate that this is, indeed, now beginning to happen. It might also be noted that the type of access agreements that are noted later in this section and in the reviews of country activity in Part 4 below effectively rely on the rewards generated by patents to establish the benefits to be shared pursuant to the Convention.

The patent rights that are recognized under other international agreements, in the WTO and the plant genetic resources sector, are discussed in a subsequent Part of this report.

2.2.2 From common heritage to national sovereignty and common concern

The move away from the common heritage position was accomplished in two ways in the Biodiversity Convention. First, the preamble only notes that the "conservation of biological diversity is a common concern of humankind." This was an implicit rejection of the common heritage approach that was promoted by several delegations early in the negotiations. The difference between these two concepts confirms the rejection of the common heritage principle. It has, in the context of the Convention, been described as follows:

In this case, "common heritage" is understood as implying a common right of access to resources and benefits deriving from the use of the resources.

.... "common concern" is understood as implying a common obligation towards an issue that is of paramount importance to the international community. (Burhenne-Guilman and Casey-Lefkowitz, p. 47-48 at notes 14 and 15)

In essence, common rights are replaced by responsibilities, the latter of which are set out in the Convention. Those relating to the IPR issues will be discussed below.

¹⁰ For example, Strauss, 1993, p. 611, argues there should have been an express recognition of such patent rights, while many South based commentators argue that the rejection of such patents should be made a priority through the Conference of the Parties established by the Convention. Eg., Nijar and Ling, 1994, p. 277.

The second key factor is found in Article 15(1) of the Convention. It expressly recognizes that states have sovereign rights over the genetic resources found in their territory, and that these resources can be made subject to national legislation. This marked a full reversal of a conception of a right to free access to genetic resources based on the common heritage concept.

Two additional points may be noted here. First, the Convention did not alter the status of real property rights that may exist in any country over genetic resources. It merely confirmed jurisdiction of the state to regulate the resources, in particular access to them by a foreign person, as they could any other resource. The relationship between private rights over resources and state laws remains a legal matter within the state. Secondly, the status of non-private community resources (indigenous or local traditional communities) is not fully addressed by the affirmation of national sovereignty. It, too, is essentially left to the national legislation of each state. Genetic resources, on the other hand, that are found within national jurisdiction and are not part of private property can be defined as part of the national property. (Svarstad, p. 50; IUCN, p. 76)

The affirmation of national sovereignty was accompanied by an additional, critical element. Article 15(5) requires that

Access to genetic resources shall be subject to prior informed consent of the Contracting Party providing such resources, unless otherwise determined by that Party.

A large number of analysts have identified this provision as the critical connection in the development of the new regime of the Convention. Hendryckx et. al. (1993), in the most detailed review of the application of the prior informed consent (PIC) concept under the Convention, argue that para. 15(5) sets out the procedural requirement for both mutually informed and mutually agreed terms of access. In classic legal terms, consent must be both informed and freely given.

One might note here that the combination of the shift to the common concern approach and the adoption of the prior informed consent procedure does not mean all access must be subject to financial or other terms. Indeed, where mutually agreed through bilateral or multilateral agreements access under the agreed circumstances could be granted at no cost. What remains central here is the free and informed consent.¹¹

By making access subject to prior informed consent, the Convention builds on the concept of environmental "rights" of a state to protect and preserve its environment that is now found in international law relating to the transboundary movement of hazardous waste, and in PIC procedures applicable to trade in hazardous chemicals. In this case, however, it is the removal of a product, not its import, which is subject to the consent. This, of course, is in keeping with the objectives of in

¹¹ Non-commercial research could be one example of such a circumstance.

situ conservation and the sustainable use of the resources. It reflects the primary management responsibility of the in situ state.

For prior informed consent to become an effective operating procedure, the country to grant access must have legal and/or policy instruments that apply to the request for access. Alternatively, a party may wish to inform the other parties that it will not require PIC under the Convention. Absent such a declaration, however, PIC obligations apply in law but may be inapplicable in practice until a mechanism for giving consent is identified by a party. (Hendryckx, 1993)¹²

This prospect has raised the question of the obligation of an importing state in relation to PIC. Several authors have suggested the need for importing states to either prohibit the import of genetic resources that have not been subject to PIC, or otherwise sanction such conduct. The most common additional sanction suggested involves the rejection of any patent application for a product or process based on an imported genetic resource obtained without prior informed consent. (Hendryckx, 1993; IUCN, 1994, p. 81; Reid et. al, 1993, p. 46) Such an approach would link the control of tangible property on the resources with the use and control of the intangible genetic information they contain.

While the national right to grant access to genetic resources is clear under the Convention, one must also note the related obligation to "endeavour to create conditions to facilitate access" and "not to impose restrictions that run counter to the objectives of the Convention." (Article 15(2)) This limits the random or capricious exercise of the rights of national sovereignty, but does not override the decision-making role of the state.

Finally in relation to the access process, there is one critical exclusion from the scope of the Convention's PIC requirement. The Convention does not apply to genetic resources that were collected prior to its entry into force and are located in gene banks or collections of plant specimens outside their country of origin. (Art. 15(3)) In these cases, the status of the genetic resources not covered by the Convention has been made subject to further review by the FAO Commission on Plant Genetic Resources.¹³

2.2.3 IPRs, technology transfer and access to genetic resources

If access to genetic resources is to be on mutually agreed terms, and through a prior informed consent procedure, what then are the elements of an agreement for the benefit of developing countries? The answer here reflects, in part, the bargain struck during the negotiations between access to genetic resources for the North and access to the rewards and benefits of the biotechnology

¹² The responses of several countries are discussed below in the review of national activity pursuant to these provisions of the Convention.

¹³ This was done through Resolution 3 of the Nairobi Final Act that adopted the text of the Convention, May 22, 1992. For developments in this regard, see the review of FAO activities in relation to the Convention, below.

sector for the South. In addition to financial compensation for access to the resources, the transfer of technology and biotechnology products and processes is foreseen in the Convention. The critical issue in the present context is whether the relevant provisions require or permit a non-consensual limitation or rejection of intellectual property rights in connection with such transfers. Note that we are presently speaking of access to technologies in the context only of an agreement on access to genetic resources. Access to technologies outside this context is considered in s. 2.2.4, below.

Prior to entering into the specific articles directly relevant to this issue, it is useful to recall the proviso of Article 1, "Objectives", that both access to the resources and access to technologies shall take "into account all rights over these resources and to technologies". This affirmation provides a sound basis for interpreting the subsequent provisions of the Convention, and from which to attempt to resolve ambiguities where they arise.

Article 15(4) requires that access be granted on mutually agreed terms. When a private company is involved in establishing such terms, a contractual basis for the ensuing action is created. Thus, a foreign country granting access cannot claim a right to remove IPR protections after the transfer of a product or process based on such mutually agreed terms. Doing so would constitute a clear breach of these terms and negate the very notion of them being mutually agreed. Now, it is clear that states have at times breached contractual arrangements with private companies for the transfer of technologies or the attraction of investments, and compensation has been difficult to achieve in some of these circumstances. If, however, the concept of mutually agreed terms is to be given its normal meaning, this situation is not accepted or endorsed by the Convention. Indeed, by placing the emphasis on mutually agreed terms for access, the Convention rejects such an approach.¹⁴

The most appropriate context for considering technology transfer under an access agreement is as a business transaction between the private party seeking access and the state and/or private party and/or indigenous or traditional community from which access is sought. The appropriate bargaining agent(s) for granting access is determined by the law of the country granting access. It is up to the participants in the negotiating process to identify the appropriate terms on which access should be granted in the commercial context that exists at the time.

Access has a commercial value to biotechnology companies. This value will vary significantly from circumstance to circumstance, based on the specific or general search that is intended and the broad or narrow availability of those resources, and on the uses to which the products will be put. Mutual agreement fixes that value for both sides in any given instance. (Reid,

¹⁴ While the area of state takings can be complicated, it is clear that the existence of a contract for the transfer of technologies on mutually agreed terms bolsters the legal position of the provider of these technologies in the event of a subsequent limitation of their rights not contemplated in the agreement. Further, the evaluation of the risks of such an occurrence is a common business issue, not unique to biotechnologies.

et. al., 1993; Downes, 1993¹⁵; Goldman, 1994) Several authors that adopt a commercial perspective to the value of access to resources on any given occasion suggest that such access is unlikely to require costs as high as the agreed withdrawal of intellectual property protection, something no company is likely to pay for access. (eg., Goldman, 1994, p. 723)¹⁶

Among the possible results of the process from the developing country perspective, access could be granted in return for financial rewards both as up front payments and as royalty payments for any marketed products, waivers of royalty payments for that country's own purchases of the product, investments in domestic capacity building including training, equipment of a general technological or biotechnological type, expansion of domestic research and sampling capacity, access to the results of the research based on the resources accessed and transfers of products and processes that result from the access.

Of this range, the Convention appears to put a premium on undertaking scientific research in the developing country providing the resource, or with their participation (Art. 15(6)), and sharing in a fair and equitable way the results of the research and benefits arising from the commercial or other utilization of the genetic resources provided (Art. 15(7)). This reflects a combination of the so-called soft technologies and hard technologies, as well as financial benefits. The first of these is placed in the context of a party endeavouring to develop and carry out such research in the developing country or with their participation. This does not create an obligation to impose such a course of action on a private company or a state entity. The second is expressly made subject, once again, to mutually agreed terms.

In addition, Article 19, paras. 1 and 2 set out further obligations to parallel the priority subjects identified by the Convention for transfer in an access agreement. Art. 19(1) requires legislative, administrative or policy steps to be taken, as appropriate, to provide for the effective participation of developing countries in the research done subsequent to access, preferably in the developing country. Again, nothing here requires a party to compel this to occur vis-a-vis a private or public sector company or agency. Art. 19(2), for its part, talks of taking all practical steps to promote access on a fair and equitable basis to the results and benefits of any research following an access agreement. As in previous articles, this is expressly made subject to mutually agreed terms.

In looking at the question of access rewards and sharing of benefits, Juma, 1993, suggests that a focus be placed on technologies for long-term capacity building, rather than short term profits for developing countries. Goldman, taking a commercial actor perspective, notes that of the types of possible transfers, those dealing with patented technologies are least likely to be favoured by business enterprises, while non-patented and financial benefits will be more favoured. (Juma, 1993,

¹⁵ David Downes, for example, provides a clear conceptualization of the process as one of the "biodiversity trade". He defines four primary elements from the Convention that constitute the main principles for the regulation of this trade: mutually agreed terms; prior informed consent; sharing of the benefits with the source countries; and sharing of the benefits with any indigenous or traditional community from the application of their knowledge. Downes, 1993, p. 26-27.

¹⁶ This area is reviewed in considerable detail in Part 3.1 of the companion Literature Review.

Goldman, 1994) There is, in many ways, a synergy between these two approaches which, despite coming from very different perspectives, both look at meeting the broadest objectives of the Convention.

It has already been noted that a key element of the process will be the implementation of domestic laws and policies to regulate the giving of consent for access. In this regard, it is possible that some access legislation could set a waiver or renunciation of patent rights as a pre-condition for access to be granted to the jurisdiction in question. One author, writing from a combined legal-business perspective, notes that any such coercive efforts are likely to be unsuccessful from a commercial perspective. (Goldman, 1994, p. 723) From a strictly legal perspective, any implementing legislation that requires such a term of agreement does not vitiate the notion of mutually agreed terms. Such legislation would, however, establish parameters within which an agreement could be reached by the state in question. This would impact on a decision by any other public or private parties to pursue or not pursue an approach to that party. While limiting the scope of an agreement, such a clause cannot "confiscate" technology from a company that does not submit to an agreement with the state in question.¹⁷

For the issues covered to this point, few commentators have shown any disagreement with the above framework for access to technologies subsequent to a prior informed consent process being followed.¹⁸ Issues have arisen, however, with respect to the impact of Article 16 both in the context of mutually agreed terms of access to the resources and the context of a desire by a developing country to access technologies outside of a consent-based approach.

Only paragraph 3 of Article 16 deals expressly with technology transfer following access. It states that the parties shall take legislative, administrative or policy measures, "as appropriate, with the aim that" developing countries that provide access to genetic resources are provided access to and transfer of those technologies that make use of such resources, "on mutually agreed terms". To this point, no concerns arise. The balance of the paragraph, however, continues to raise some objections, most notably the final reference to paragraph 16(5). It specifies that technologies, which includes biotechnologies, covered by patents and other intellectual property rights should be included in the technologies to which access is provided. This is to be "in accordance with international law and consistent with paragraphs 4 and 5 below." While "in accordance with international law" would appear to support the maintenance of intellectual property rights, or at the very least the position that the Convention does not negatively impact them, the reference to paragraph 5 is seen by some as raising doubts. This will be turned to shortly.

¹⁷ An alternative concern not raised in the reviews of the Convention seen by the present author is that applications of the access and prior informed consent rules could create a non-violation impairment of acquired rights under GATT and TRIPS. This concern might be raised in specific circumstances. An analysis of its possible role is beyond the scope of this more general review.

¹⁸ The complementary report on the Literature Review provides a more in depth review of the full range of commentaries on this point.

Article 16(4) also refers to the parties taking legislative, policy or administrative measures, as appropriate, "with the aim that the private sector facilitates access to, joint development and transfer of technology" for the benefit of both governmental institutions and the private sector in developing countries.¹⁹ The notions of "as appropriate" and "facilitates" lead to the conclusion that an obligation to impose terms on their industries is not being established here for developed countries. Methods to encourage decisions that lead to transfers on terms agreed by the private parties should not, in this context, be objectionable, and do not deny any rights to the private party. Furthermore, the reference to joint development indicates the reliance here on an active participation of the private parties that might be involved, a notion not well supported by the actual or potential removal of their rights.

This leads, inexorably, to the provision which has led to the most controversy, particularly for the United States, Art. 16(5). Two questions will be explored here. First, does Art. 16(5) override the reasoning reflected above that suggests that no impact on intellectual property rights arises from the text of the Convention in the context of an agreement on access to genetic resources? Second, does Art. 16(5) in itself authorize the limitation or removal on a non-consensual basis of intellectual property rights under the Convention, outside an access agreement? Phrased in GATT language, does Art. 16(5) allow for compulsory licensing of technologies or products for the conservation of biodiversity or its sustainable use?

2.2.4 IPRs and technology transfer: Article 16(5)

Art. 16(5) has been described as containing "perhaps the most objectionable language on intellectual property rights in the Convention." (Chandler, 1993, p. 163) It reads:

The Contracting Parties, recognizing that patents and other intellectual property rights may have an influence on the implementation of this Convention, shall cooperate in this regard subject to national legislation and international law in order to ensure that such rights are supportive of and do not run counter to its objectives.

It is argued that this provision "allows the interpretation" by developing countries that Parties have an obligation to ensure that intellectual property rights do not interfere with the transfer of technology and the sharing of profits. (Chandler, 1993, p. 163; see also Goldman, 1994, and Strauss, 1993) Lying behind this is the consternation of the US and some other countries, and the biotechnology industry, that the provision did not expressly affirm their view of the positive role of IPRs in supporting technology transfer:

¹⁹ The funding of joint development projects in part through the funding mechanism was identified at the first Conference of the Parties as a priority area for use of the funds to be available through the G.E.F.. (UNEP/CBD/COP/1/17, 28 Feb. 1995, p. 33-34.)

Article 16 fails to recognize the positive role of intellectual property systems in facilitating technology transfer and cooperative research and development by private entities.²⁰

The opening words of paragraph (5) do not make any affirmation, either that IPRs are or are not supportive of the objectives of the Convention. This reflected the bitter divisions on the role of IPRs in the North-South context, a division which was equally felt in the GATT negotiations. This being so, it is difficult to see how an obligation can be found to change the system of IP protection when the view is split that it needs to be changed, and that split is clearly not resolved by the language of the Convention. Further, the only operative verb in the paragraph requires the parties to "cooperate". This would not appear to create either an obligation for developed countries to remove IPRs, or a unilateral right to remove them by developing countries.

Para. 16(5) is also seen by those who view the Convention as putting into doubt the strength of IPRs as weakening the requirement of Art. 16(2) that

in the case of technologies subject to patent and other intellectual property rights, [such] access and transfer be provided on terms which recognize and are consistent with the adequate and effective protection of intellectual property rights.

The phrase "adequate and effective protection" is directly from the international trade law area, in particular the Agreement on Trade Related Aspects of Intellectual Property Rights. While the GATT Uruguay Round negotiations concluded only in December, 1993, the negotiations on the so-called TRIPS Agreement had in fact concluded in December of 1991. The language on adequate and effective protection was thus incorporated into the Biodiversity Convention to reflect and re-enforce the same concept. The reason for the concern over the efficacy of these words, however, is the continuing words of the paragraph, which state that

The application of this paragraph shall be consistent with paragraphs 3, 4, and 5 below.

Thus, it is argued, the uncertainties of para. 16(5) are introduced into para. 16(2) as well.

There is little doubt, as the IUCN review of the Biodiversity Convention points out, that the full text of Article 16 is circular and convoluted. (IUCN, 1994, p. 84) Indeed, there is virtually no review of the Convention that would not concur with this view. This, however, does not mean that it leads to the conclusion that business can be stripped of rights held in such technologies solely for this reason. Rather, one must attempt to make the best sense of the circularity and ambiguity that is presented. For example, Chandler argues that the term "mutually agreed terms" in Art. 15(4) is restricted because the transfers of technology under Art. 15(4) "shall be on mutually agreed terms and subject to the provisions of this Article." This last proviso, she notes, brings in the text of Art.

²⁰ This is from the US statement at the conclusion of the final negotiations in Nairobi, as quoted from Chandler, 1993, p. 162. Melinda Chandler was the legal advisor to the US negotiating team for the Convention.

16(5) because all of Art. 16 is referenced in para. 15(7) which is part of the Article referred to in 15(4). This connection is then used to reduce the application of the single, stand-alone paragraph of Article 15(4), despite its conjunctive "and". This conjunctive, however, appears to require a reading of the full text that supports the simultaneous application of both conditions if this is possible. And it is, but only if the interpretation that paragraph 16(5) does not support the unilateral removal of intellectual property rights is taken. This approach, it is suggested here, is also consistent with the words of Article 1 of the Convention that give an equal level of respect to rights to the genetic resources and rights to the technologies.

2.2.5 The recorded views of participant countries²¹

Melinda Chandler suggests that a number of states took the interpretation at the close of negotiations in Nairobi that the negotiations had led to the opposite result of that suggested above. (Chandler, 1993, p. 163) It is unclear, however, that the formal statements on the adoption of the Convention text (upon signature or ratification) support this contention, though it is clear they reflect some of the ambiguity of the text and discomfort on the part of some with the effective result.

As at July 19, 1995, there were 118 parties to the Convention. Of these, twelve had made declarations on ratification or acceptance of the Convention. Just three of these refer to the IPR issues.²² These are from France, Switzerland and the European Community.

Each of these countries affirms the importance of intellectual property rights in promoting research and technology transfer in the biotechnology field. Each states that these rights are not impacted by the Convention. France and the EC, for example, both state that technology access and transfer "will be carried out in accordance with article 16 of the said Convention and in compliance with the principles and rules of protection of intellectual property." The Swiss declaration, which repeats its statement on adoption of the text in Nairobi, also affirms the need to protect intellectual property rights, and the contractual basis that the Convention establishes for doing so. Switzerland goes on to state, however, its readiness to consider publicly held technologies in a more flexible manner. This possibility is, of course, open to all countries which have research and development activity in the public sector. None of these declarations interpret the Convention to require any other form of private sector technology transfer. Each, in fact, indicates the compatibility of the contractual process with the provisions of the Convention.

²¹ The formal statements of the negotiating parties, and statements on signature and ratification are of uncertain legal value and weight. The purpose of this brief review of these statements is not to analyze the weight they have in any dispute resolution context, but to review the sense they give to the final result.

²² Source: Multilateral Treaties Deposited with the Secretary General, Status as at 31 December, 1994 (ST/LEG/SER.E/13)

The declarations made on the adoption of the Convention do include some additional comments from developing countries.²³ Malaysia, for example, stated that the terms for technology transfer found in Art. 16(2) did not "fully reflect" its position that requires such transfers to be on preferential and concessional terms. This repeated its preceding statement during the final plenary session of the negotiations, prior to the formal adoption of the Convention in the Nairobi Final Act, with the exception that on that occasion Malaysia specifically spoke for the ASEAN nations. This position was also taken by the Philippines.

Other statements were made at the conclusion of the negotiations as well.²⁴ Australia stated that nothing in the Convention required or mandated any actions in violation of international laws or agreements on intellectual property rights.

Ethiopia stated its dissatisfaction with the provisions protecting patents and other intellectual property rights without similar protection for informal innovations. It suggested that the result in Art. 16(2) actually opened the door for the developed countries to take such technologies out of reach of even those countries which created the original resources and innovations. Ethiopia also directly suggested an amendment to the text for consideration at a later date to reverse this result.

In fact, the only formally recorded statements or declarations to actually question whether intellectual property rights were fully protected were by the United States. At the conclusion of the negotiations, the US affirmed its view that the respect of intellectual property rights was essential for the development and transfer of technologies, and expressed its concern that this was not expressly recognized in Article 16. It stated that the US delegation found Article 16 "potentially deficient in the protection of intellectual property rights." At the adoption of the Nairobi Final Act, the US stated that it found the treatment of intellectual property rights "particularly unsatisfactory", as well as other provisions on technology transfer, biotechnology and financing under the Convention.

This position has been maintained, and continues to be a barrier to American ratification of the Convention. The US has formally urged the parties to clarify the weaknesses it finds in the Convention through a Protocol which it would hope to see concluded before it ratifies.²⁵

²³ Report of the Intergovernmental Negotiating Committee for a Convention on Biological Diversity, UNEP/Bio.Div./N7.INC.5/4 (1992).

²⁴ These are reported in UNEP/Bio.Div/N7.INC.5/4, Annex.

²⁵ From a joint statement by UN Amb. Madeleine Albright and Counsellor of the State Department Tim Wirth, on the signing of the Convention by the US in June, 1993. As reported in Strauss, 1993, p. 608-9.

2.2.6 Conclusions on the Convention and Intellectual Property Protection

To return then to the two questions posed earlier, it is submitted here that the Convention text, in particular Art. 16(5), does not override the clear references to mutually agreed terms and recognition of intellectual property rights. This is so in circumstances of access to technology both following an agreement on access to genetic resources and for technology transfers under the Convention, including where funded fully or in part by the Global Environment Facility.

This section will close with a representative sample of quotations that summarize the different legal perspectives that are found today.²⁶ It is clear from this sampling and from the ongoing debate, that continued discussions on the issue are inevitable, particularly with the continued US non-ratification of the Convention. We begin with Melinda Chandler:

At best, and with the most charitable reading, articles 15 and 16 embody an internally inconsistent, abominably drafted series of legal obligations allowing each camp to interpret the articles in its own (diametrically opposed) way. At its worst reading, Article 15 and Article 16 fundamentally alter intellectual property rights protections as we now know them and impose upon a Contracting Party an amorphous, undefined legal obligation to interfere in purely private business transactions. (Chandler, 1993, p. 165)

The review of these provisions by the African Centre for Technology Studies concludes that:

The US fear is dispelled by noting that in effecting technology transfer from the private sector, Art. 16(4) enjoins the parties to "abide by the obligations included in paragraphs 1, 2, and 3 [of Art. 16]" which, as we have indicated, are resolved in favour of according to patents and other intellectual property rights "adequate and effective" protection.

.....

Art. 16(5) is, broadly speaking, preambular and somewhat declaratory in character and has greater moral and political than legal force....Art. 16(5) should have been more active, for instance, indicating areas of cooperation on modalities for making national legislation and international law responsive to the imperatives of equitable IPR systems. One such modality is working towards some common understanding on issues of patentability, duration of patents, the attendant issue of revising the Paris Convention to reflect new realities and developments in international law and relations in the field of environment and development. (ACTS, 1993, p. 5)

²⁶ This is just a sample of the perspectives raised on the Convention in the companion Literature Review, section 3.1.

Hanne Svarstad provides a negotiation oriented appraisal:

Although the text is vague, it may also be used to argue against IPRs....if Southern countries can maintain pressure for its suitable interpretation, and clearly show that IPRs work against the interests of biological conservation, then this clause could well work to their advantage. Industries have little reason to fear from the Convention's stance on IPRs, and developing countries are likely to gain only small reductions of formal barriers against transfer of technology. (Svarstad, p. 62)

And finally, Michael Gollin argues:

The section is so convoluted and ambiguous that the obligations of a signatory nation are not clear. As a result, the United States initially made a worst-case interpretation of the language.

However, the language of Article 16, read in context, lends itself more easily to an interpretation that would promote productive international agreements without requiring them. In particular, any country that interprets Article 16 as requiring involuntary transfer of technology must be prepared for the counter-argument that the similar language in Article 15 requires involuntary transfer of genetic resources, a result no source country would happily accept. (Gollin, 1993, p. 295, original emphasis)

2.3 Indigenous and local community knowledge and IPRs

In addition to the above issues concerning intellectual property, the issue of indigenous and local community knowledge is raised by the Convention. Paragraph 12 of the preamble recognizes the desirability of sharing equitably the benefits arising from the use of traditional knowledge.

Art. 8(j) establishes an obligation to respect, preserve, and maintain knowledge, practices and innovations relating to the use and conservation of biodiversity of indigenous peoples and local, traditional communities. It also calls for the promotion of this body of knowledge, practice and innovation, with the participation of indigenous peoples, and encourages the equitable sharing of the benefits of such use. All this is, however, made subject to the national legislation of the parties. As part of the sustainable use obligations, parties are required by Art. 10(c) to protect and encourage customary use of biological resources that are compatible with sustainable use requirements and conservation. These obligations reflect the link between biological diversity conservation and the role of indigenous peoples and traditional communities in nurturing and maintaining this biodiversity. They work to support the linkages between biological and cultural diversity as part of a critical process, with the preservation of each relying on the preservation of the other.

Article 17(2) calls for the exchange of indigenous knowledge as part of the general information exchange to be facilitated under the Convention. Article 18(4) calls for the parties to encourage and develop methods of cooperation for the development and use of technologies, including indigenous and traditional knowledge. This could include cooperation in the training and exchange of personnel.

Each of these references to indigenous and traditional knowledge raises the prospect of specific rights and protections for indigenous and traditional/local groups, but none of them actually provide such rights or protections. In the case of traditional agricultural practices, this gap is expressly recognized in Resolution 3 of the Nairobi Final Act that was adopted with the text of the Convention. Paragraph 4(b) of the Resolution expressly calls for further consideration within the FAO of the question of farmers' rights, which are designed primarily for the protection of traditional farming practices.

In the case of the use and sharing of non-agricultural plant knowledge and practices, there is no formal international process established to address this situation. Implementation is left to be determined by each individual party. This is due in part to the considerable concern for the modalities of identifying and rewarding indigenous knowledge in such areas as traditional medicine. Knowledge may not be confined to a single community or person, it may cross national boundaries, or it may be publicly available. Indigenous or traditional knowledge may also already be incorporated into other applications, as is often the case with medical drugs. (Reid et. al., 1993)²⁷

Art. 8(j), in particular, "encourages" the equitable sharing of benefits of the use of this knowledge. In developed country terminology, such encouragement usually takes the form of a rights-based system, despite the fact that most intellectual property systems do not readily accommodate indigenous or traditional knowledge, or the process of innovation likely to prevail in these communities. This raises the importance of the limitation found in Article 8(j), that it is subject to national legislation, and hence may be interpreted or applied in a restricted manner. (IUCN, 1994, p. 49)

A second and related feature of this is the inclusion of indigenous and traditional peoples in the process of prior informed consent. Many reviewers of the Convention suggest that the provisions on indigenous knowledge and participation call for the inclusion of these groups in any discussions on access to the resources to which the knowledge applies. An additional factor is the access to lands which they occupy. (eg., IUCN, 1994, p. 49, 80-81, Downes, 1993)

This view of implementing the decision-making role of indigenous peoples is consistent with the broader developments throughout the UNCED process concerning indigenous peoples. Most notable here are the Rio Declaration, Principle 22, and Agenda 21, Chapter 26. Both of these stressed the need for indigenous and local community participation in decisions relating to their communities and lifestyles, and the effective preservation of their way of life and the resources it

²⁷ The range of issues associated with indigenous knowledge and intellectual property are fully considered in the Literature Review, sections 3.1 and 5.3.

depends on. Chapter 26, in particular, also placed this in the context of the protection of intellectual and cultural property rights. (Mann, 1993, pp. 146-148)

These factors are now leading some countries to adopt or consider policies and legislation that includes indigenous peoples and traditional communities as part of the access regime. (See the country reviews, below.) Indigenous, environmental and professional associations active in the field have also established declarations and rules of conduct that support such regimes and the indigenous and traditional communities role in them. The trends indicated in this area are for such developments to continue.

To assist in the consideration of this issue, the Secretariat of the Biodiversity Convention has prepared a review of the issues and possible approaches to addressing them.²⁸ These approaches include, *inter alia*:

- state recognition of communal rights
- state recognition of appropriately defined forms of indigenous property rights, including over access to their lands
- better access to the formal legal system
- access to financial and technical resources under the Convention for their own capacity building
- encouraging the marketing and production of their products rather than Western derivatives of them.

The Secretariat's note also reviews a number of the international agreements and non-binding declarations of governmental and non-governmental bodies, including indigenous groups and professional associations that have recognized the need and equity in this area.

The Biodiversity Convention has not expressly required the alteration of national or international law in this area. Nonetheless, it has clearly put into play an element that has already led to initial developments in this regard, and has the growing potential to lead to many more.

²⁸ UNEP/CBD/IC/2/14, 20 May, 1994, "The rights of indigenous and local communities embodying traditional lifestyles: experience and potential for implementation of Article 8(j) of the Convention on Biological Diversity". This note was prepared at the express request of Nigeria on behalf of the African group, at the first session of the Intergovernmental Committee in October, 1993, convened to work on the Convention prior to its entry into force. The literature on this issue is now large, and beyond the scope of this report.

2.4 Related activity within the Biodiversity Convention and Secretariat since 1992²⁹

It has already been noted that the intellectual property issues were among the most divisive of the Biodiversity negotiations. For many, this has led to a desire to have a "cooling off" period on these issues, and they have not been directly tackled by the parties in a substantive way since the conclusion of the Convention negotiations.

Still, some issues have been looked at by the Secretariat, as we have already seen in the case of the note on indigenous knowledge. Other issues have been treated less directly in the course of related work under the Convention. And a process for addressing the central issues over the next three years has been established by the first Conference of the Parties. This section summarizes these activities.³⁰

Resolution 2 of the Nairobi Final Act included an invitation for the Governing Council of the United Nations Environment programme to consider requesting its Executive Director to convene meetings of an Intergovernmental Committee on the Convention on Biological Diversity in 1993. This Committee was to consider a number of issues relevant to the initiation of the Convention and the first meeting of the Conference of the Parties. The first such meeting was convened for October, 1993.

In preparation for this meeting, the Executive Director had also convened four expert panels to review issues of relevance to the progress on the Convention. Two of these panels considered issues related to the IPR provisions, but in a limited way. The report of Panel II concerned the evaluation of the economic implications of the biological diversity conservation and its sustainable use. It touched on the recognition of indigenous contributions and value added concepts in relation to the use of their knowledge. It made no specific recommendations on the issues of protecting indigenous knowledge through a rights-based system of any type.³¹ The report of Panel III dealt with possible modalities for transfers of technology, including a clearinghouse mechanism, but did not review the provisions of the Convention on IPRs. Funding for IPR protected technologies as

²⁹ The following section is based on the documents of the Convention and the Secretariat, and on personal interviews with various officials, as noted in the methodology section. This section has been updated to reflect the input into the second Conference of the Parties in November, 1995, and the resulting Decisions.

³⁰ Summary is the proper notion here. No activities to date have led to any official interpretive documents on the key issues. Rather, the process has been more educational and organizational in nature. These are the elements that will be summarized. Fuller reviews of the activities under the Convention through to the first meeting of the Conference of the Parties, can be found on a yearly basis in Gunther Handl, ed., *Yearbook of International Environmental Law*, Vol. 4, 1993, pp. 245-249, and Vol. 5, 1994, forthcoming. (Advance copy provided by the editor)

³¹ UNEP/Bio.Div./Panels/Inf2, April, 1993.

part of technology transfer arrangements was noted as a means to support the transfer of such technologies.³²

The first session of the Intergovernmental Committee produced no substantive results. It delayed all decisions, beyond the organizational structure of the Committee itself, to its second meeting. This session did, however, produce the African request for the Secretariat to prepare a report on indigenous and farmers rights, as already noted. It also convened an Open-Ended Intergovernmental Meeting of Scientific Experts on Biological Diversity, as a prelude to the Subsidiary Body on Scientific, Technical and Technological Advice envisaged by the Convention. (SBSTTA, Art. 25 of the Convention)

This Committee met in Mexico in April, 1994. It did consider indigenous knowledge in the context of technologies for the conservation of biological resources. This was in the context of an agenda item on the ways and means to integrate indigenous and traditional knowledge into modern management practices. The Committee reached two conclusions. First, that there was a need to define, with these communities, how modern tools could assist them in strengthening their own strategies for the conservation and sustainable use of biodiversity, while fully respecting their intellectual and cultural property and their own vision of development. Second, there was a recognition of the need to recognize the value of traditional knowledge, and "subsequently to develop a mechanism for appropriate protection and compensation for such knowledge." No specific suggestions, beyond the need for education and a full involvement of indigenous and traditional peoples in the process, were made, however.³³

More broadly, the Committee also produced a catalogue of technologies that could be used for biodiversity conservation. This has value in adding to the range of tools applicable to this side of the technology transfer agenda, as opposed to biotechnology processes and products. As such, it can add to the range of technologies that can be considered in the capacity building context of an access agreement or other processes for technology transfer.

The second meeting of the Intergovernmental Committee focussed on the preparation of the First Conference of the Parties. The specific agenda items for that meeting designated by the Convention did not directly include the IPR issues. The second session did, however, note the need to consider the equitable sharing of benefits in relation to *ex situ* collections of biodiversity collected prior to the entry into force of the Convention, the work being continued in the FAO. It also noted the importance of recognizing the innovations of local and indigenous people. Views on the need for, and appropriateness of some form of intellectual property rights were expressed, including on

³² UNEP/Bio.Div./Panels/Inf.3, April, 1993

³³ "Report of the Open-Ended Intergovernmental Meeting of Scientific Experts on Biological Diversity", UNEP/CBD/IC/2/11, especially Annex VII.

the need for a legally binding instrument in this area. Clarification of Art. 16(5) was also raised as an issue.³⁴

Access to genetic resources, access to and transfer of technologies, and indigenous knowledge, i.e., the IPR related issues, were referred to the first Conference of the Parties in the context of setting the medium term agenda for the operation of the Convention for the three year period of 1995-1997. The Conference of the Parties (COP) included five items of relevance, two for each of the first two years to follow, and one for the last.

The second COP, held in Jakarta from 6-17 November, 1995, considered, through two agenda items, the issue of access to genetic resources and issues relating to intellectual property and technology transfer.³⁵ The discussions focussed on documents that compiled:

- existing legislation, administrative and policy information on access to genetic resources and the equitable sharing of benefits derived from their use;³⁶ and
- information provided by governments and international organizations regarding policy, legislative instruments or administrative measures related to intellectual property rights under Article 16, and to access to and transfer of technologies that make use of genetic resources.³⁷

Each of these documents reflect previous work of the Secretariat on the substance of these issues, in keeping with the analysis presented above. They then provide additional examples and information on developments in the area. No substantive decisions were taken on these issues at COP 2. Further studies on these and related issues were commissioned by the Parties. Broad stakeholder discussions were also called for, as well as more integrated preparatory work by the Convention Secretariat with the Committee on Trade and Environment of the WTO.

The medium term plan calls for the third COP, in 1996, to consider two items again.³⁸ The first is the implementation of Art. 8(j) on the knowledge, innovations and practices of indigenous and local communities. Elements related to this item are part of the broad discussion and study

³⁴ UNEP/CBD/IC/2/L.3.

³⁵ Annotated Provisional Agenda, Second Conference of the Parties, items 7.1, 7.2. UNEP/CBD/COP/2/1/Add.1, 10 August, 1995.

³⁶ "Access to Genetic Resources and Benefit Sharing: legislation, Administrative and Policy Formation", UNEP/CBD/COP/2/13, 6 October, 1995. The follow-up work will expand on this report.

³⁷ "Intellectual Property Rights and Transfer of Technologies Which make Use of Genetic Resources", UNEP/CBD/COP/2/17, 6 October, 1995. The follow-up work will expand on this report.

³⁸ *Ibid*, paras. 6.5 and 6.6, p. 64.

process noted above. The second item is again titled access to genetic resources, and calls for a compilation of views of the parties on possible options for developing national legislative, administrative or policy measures, "as appropriate", to implement Article 15. In this context, the previous year's work can be seen as setting the stage for year two of the medium term plan, and providing background information for the consideration of this item. The further studies will contribute to the discussion on this item. One can expect, however, that some states will be proceeding to develop and institute access legislation or policies prior to this discussion taking place, as has indeed been the case to date.

The 1997 program calls for consideration of measures to promote and advance the distribution of benefits from biotechnology in accordance with Article 19.³⁹

Two points may be highlighted here. First, there is an incremental framework, but also a potentially disconnected one. The second year shows a separation of the issues of the implementation of Art. 8(j), on indigenous knowledge and sharing of benefits, from the agreement on access to genetic resources. Many commentators, however, believe that indigenous rights and benefits can be best protected or respected through the access process. Both of these issues are then separated by a year from the consideration of Article 19, and the distribution of benefits following access to foreign resources. Arguably, however, this provides the final link in the access agreement contemplated by Art. 15. These separations are not, of course, fatal. Still, they may require some consideration to avoid artificial barriers to a comprehensive discussion of the issues. The study program requested by the Parties should contribute to avoiding such a result.

Second, and for the time being, the attention of the parties is focussed, from a further negotiating standpoint, on a Protocol on Bio-Safety. Clear divisions on the scope and content of such a Protocol will need to be resolved. It is expected that this situation will delay any discussion on developing an official instrument under the Convention on the access/IP issues, whether as a formal legal instrument such as a Protocol, or a soft law instrument such as guidelines or model laws. As a result, and considering the schedule of the medium term plan, bilateral processes will have a significant opportunity to develop, both where formal legislation or policies on access to resources exist and where they do not. Some residual focus can also be expected to emerge on the responsibility of the developed countries to support the PIC principle and process during this period.

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3.0 THE FAO AND THE GLOBAL SYSTEM FOR THE CONSERVATION AND UTILIZATION OF PLANT GENETIC RESOURCES FOR FOOD AND AGRICULTURE

Summary:

The FAO, which has had responsibility for global conservation of plant genetic resources for food and agriculture, continues to serve as the primary forum to address issues of access to plant genetic resources, especially those ex situ collections that existed prior to the adoption of the Biodiversity Convention, and the issue of Farmer's Rights. This study reviews the regime established by the FAO concerning conservation of and access to these resources, and proposals for revision of this regime.

Since 1983, all the activities of the FAO have been in furtherance of its Global System for the Conservation and Utilization of Plant Genetic Resources, intended to promote conservation and sustainable use of plant genetic resources through international cooperation. The study reviews the various elements of the Global System, of which the most important for present purposes are the 1983 Undertaking, the Commission on Plant Genetic Resources ("CPGR", a permanent intergovernmental forum on plant genetic resources), and the International Code of Conduct for Plant Germplasm Collecting and Transfer.

The 1983 International Undertaking on Plant Genetic Resources, which for ten years was the only international agreement governing terms of access to plant genetic resources for food and agriculture, was based on "the universally accepted principle that plant genetic resources are a heritage of mankind and consequently should be available without restriction." (Article 1) This unrestricted access was qualified, however, by other provisions in the Undertaking that set out alternative ways in which samples of genetic resources could be made available: free of charge, on the basis of mutual exchange, or on mutually agreed terms.

The "free access" provisions of the Undertaking were then further limited by three resolutions, adopted after 1983 and attached as annexes to the Undertaking, which sought to balance concerns expressed by developed and developing countries by providing for both plant breeders' rights and farmers' rights.

In November, 1993, the FAO adopted a Code of Conduct for Plant Germplasm Collecting and Transfer, a voluntary code that establishes minimal standards for the issuance of permits and licences for the collection of plant germplasm. Based on the "common concern of mankind" and "national sovereignty" principles, rather than the "common heritage" one, the Code encourages states to establish systems for the issuance of permits to collectors, sets standards of conduct for the collectors (to protect the resources), and asks users to consider providing some form of compensation to local communities, farmers and the source country, on mutually agreed terms.

The FAO is currently engaged in revising the 1983 Undertaking, in accordance with the Biodiversity Convention, and for the realization of Farmers' Rights. Studies prepared in anticipation of these discussions, recognize that plant genetic resources for food and agriculture may require fundamentally different solutions from other genetic resources, to ensure their conservation, development and availability, and the fair and equitable sharing of benefits derived from their use. Their history, geographic location, and the great inter-dependence among nations for these resources, combine to create a unique problem that must be addressed on its own terms.

The legal status of the ex situ collections of plant germplasm remains unsettled. The study outlines the possible interpretations of the applicable regime, and options being considered to govern access to the germplasm in such collections. Since 1990, the International Agricultural Research Centres (IARCs) have taken the position that they are not the owners of the germplasm in their collections, but that they hold them in trust on behalf of beneficiaries, who have been variously identified as humanity, developing nations, the farming communities, and research workers. The Centres take the position that the material stored is to be made available without restrictions, and that no intellectual property rights are to be sought over such material. Material transfer agreements are to be used to prevent third parties subsequently claiming intellectual property rights in the material.

A recent meeting of the CPGR Working Group studying these issues was unable to reach a consensus on how the 1983 Undertaking should treat material stored in germplasm collections, in particular material acquired before and after the entry into force of the Biodiversity Convention. This material could be viewed as outside the Convention, and freely available as part of the heritage of mankind; or, as outside the Convention, with the host country able to legislate on ownership and conditions of access; or, as subject to the country of origin of the resource, so that the permission of the country of origin is required for the release of genetic resources from pre-existing collections. Difficulties of identifying the country of origin have been highlighted.

The issue of Farmers' Rights has been of central importance, particularly as plant breeders' rights are strengthened worldwide through agreements such as the TRIPs chapter of the Uruguay Round. Continued attention is being given to implementing these rights; the issues to be addressed are described below.

3.1 Background

Concern about conservation of the global plant genetic resources so crucial to the agricultural future of the world, has been mounting for many years. The threat of genetic erosion compelled a group of 41 individuals, from diverse countries and backgrounds, to issue an alert to the international community in 1991, that the future of the food and agriculture sectors was seriously

endangered.⁴⁰ This alert was conveyed strongly at UNCED, and was influential in the final negotiations on the Biodiversity Convention.

Historically, international efforts to ensure the conservation of plant genetic resources for food and agriculture have been on-going from several institutional centres: the Food and Agriculture Organization of the United Nations (FAO); the Consultative Group for International Agricultural Research (CGIAR) and the International Agricultural Research Centres (IARCs); and the International Board for Plant Genetic Resources (IBPGR), which later became the International Plant Genetic Resources Institute (IPGRI).

A number of articles and books trace the detailed history and, at times, conflicting jurisdictions and activities of these various organizations, and this will not be repeated here.⁴¹ (See, eg, Lacy, 1995; Juma, 1989; and Frankel, 1985-87.) Suffice to say that today, the FAO is the principal international organization with responsibility for global conservation of plant genetic resources for food and agriculture.

In 1983, the FAO decided to establish a permanent intergovernmental forum on plant genetic resources, the Commission on Plant Genetic Resources (CPGR). It also adopted a formal framework to govern the exploration, use and conservation of plant genetic resources, known as the International Undertaking on Plant Genetic Resources ("the 1983 Undertaking"). Together, the CPGR and the 1983 Undertaking formed the two essential institutional elements of the new Global System for the Conservation and Utilization of Plant Genetic Resources, initiated to promote the conservation and sustainable use of plant genetic resources through international cooperation. In essence, all subsequent activities of the FAO to date have been in furtherance of this Global System.

While there are important differences between the Global System and the regime under the Biodiversity Convention -- notably, the 1983 Undertaking was based on the principle that plant genetic resources are part of the "common heritage of mankind," available without restriction, in contrast to the "common concern" and "national sovereignty" principles of the Biodiversity Convention -- at the time of approval of the Biodiversity Convention, the convention negotiators officially recognized the Global System as the appropriate framework within which to address outstanding issues relating to plant genetic resources for food and agriculture.⁴² These have included issues of access to certain plant genetic resources, especially those *ex situ* collections that existed prior to the adoption of the Convention, and the issue of Farmers' Rights, which concerns the ability

⁴⁰ This was issued by the participants in the Keystone International Dialogue Series, after their third and final plenary session. This is discussed at greater length below.

⁴¹ A more detailed discussion of the history of international organizational efforts to conserve plant genetic resources for food and agriculture, and the relationships between the various organizations, may be found in the companion study, *Intellectual Property Rights, Biotechnology and the Protection of Biodiversity: Literature Review*.

⁴² See: Resolution 3 of the Nairobi Final Act of the Biodiversity Convention, negotiated and approved along with the Biodiversity Convention.

of farming communities (especially local and indigenous communities) to share in the benefits derived from the plant genetic resources that they have maintained.

This section will describe the 1983 Undertaking and the other elements of the Global System, focusing on the regime they establish to govern issues of *access* to plant genetic resources for food and agriculture, and the *rights* that may be claimed in the tangible and intangible property in those resources. The study will go on to outline current proposals to revise the 1983 Undertaking, to bring it into accordance with the principles set out in the Biodiversity Convention, as well as proposals to realize the concept of Farmers' Rights.⁴³

3.2 The 1983 FAO Undertaking

The International Undertaking on Plant Genetic Resources ("the 1983 Undertaking") was adopted in August, 1983⁴⁴ as a non-legally binding agreement, "to ensure that plant genetic resources of economic and/or social interest, particularly for agriculture, will be explored, preserved, evaluated and made available for plant breeding and scientific purposes." The definition of "plant genetic resources" (Art. 2) encompassed both the new products of biotechnology (commercial varieties and breeding lines), and farmers' varieties and wild materials. It was the first comprehensive international agreement addressing plant genetic resources; and for almost ten years, it served as the only international agreement establishing terms of access to these resources.

Notably, the Undertaking was based on "the universally accepted principle that plant genetic resources are a heritage of mankind and consequently should be available without restriction." (Article 1) This unrestricted access was qualified, however, by other provisions in the Undertaking that set out alternative ways in which samples of genetic resources could be made available: free of charge, on the basis of mutual exchange, or on mutually agreed terms. In other words, even within the 1983 Undertaking the concept of "free access" was not without ambiguity. (Fraleigh, 1991)

The Undertaking was adopted with reservations from eight countries: Canada, France, Germany, Japan, New Zealand, Switzerland, the United Kingdom and the United States, who were concerned about the possible scope and implications of the free access principle.⁴⁵ To overcome these reservations, three complementary resolutions were negotiated and adopted unanimously by the FAO Conference. (These are now annexes to the Undertaking.) The first provided that plant

⁴³ The following sections report on developments within the international community relating specifically to plant genetic resources for food and agriculture. Interested readers are referred to the companion literature review for a conceptual discussion of the ideas relating to these developments, and for greater detail on the history and evolution of the various international instruments discussed in the following pages.

⁴⁴ FAO Conference Resolution 8/83.

⁴⁵ Of these, Canada, Japan and the United States have still not adhered to the International Undertaking.

breeders' rights under UPOV 1978 were not inconsistent with the Undertaking, and also, as a counterbalance, recognized farmers' rights; the second elaborated on the concept of farmers' rights, and provided for the vesting of such rights in the international community as trustee "for present and future generations of farmers"; and the third provided that "breeders' lines and farmers' breeding material should only be available at the discretion of their developers during the period of development."

The third resolution also endorsed the idea of implementing Farmers' Rights through an international fund on plant genetic resources, administered by the CPGR, which would support plant genetic conservation and utilization programmes, particularly in developing countries. Resources for the fund were to be "substantial, sustainable and based on the principles of equity and transparency."

A background paper prepared by the CPGR for the current (June, 1995) session notes that the agreements embodied in these resolutions led to new qualifications on the principle of unrestricted access, in four ways:

- by affirming the sovereign rights of countries over their plant genetic resources;
- by clarifying that "free access" does not necessarily mean "free of charge" both plant breeders' rights and farmers' rights allow for some form of compensation;
- by limiting the benefits of the Undertaking to those countries that adhered to it; and
- by limiting the scope of the free access provision, such that breeders' rights and farmers' rights were excluded. (FAO, 1995, Item 8(a), ¶ 9.)

The paper goes on:

The process of developing the Undertaking through agreed interpretations, in line with the aims of the original text, has sought to develop and maintain a balance between access to the new products of biotechnology (commercial varieties and breeders' lines) on the one hand, and farmers' varieties and wild material on the other, and the interests of developed and developing countries, by balancing the rights of breeders (formal innovators) and farmers (informal innovators). However, while the rights of breeders, already enforced in many industrial countries, are being strengthened through revisions of the UPOV conventions, as well as through national and international agreements on intellectual property rights, including patents, Farmers' Rights are yet to be implemented, and the international fund foreseen in Resolution 3/91 is yet to be established. (FAO, 1995, Item 8(a), ¶ 10.)

This attempt to balance the divergent rights and interests continues today, with the current discussions on the proposed revision of the 1983 Undertaking. In addition to continuing attempts to reconcile the interests of plant breeders rights, which give rise to formal intellectual property rights, and the interests of farmers and local communities, whose resources may be used in such breeding, the negotiators also face the need to reconcile the historical "common heritage" approach to plant genetic resources enshrined in the 1983 Undertaking, with the "common concern" but state-controlled approach reflected in the Biodiversity Convention.

3.3 Other Aspects of the Global System

In recent years, the FAO's Global System has developed and evolved to encompass a number of international agreements, technical mechanisms and global instruments, at various stages of development. As will be seen, each builds on and elaborates the others, in an integrated system for conservation of plant genetic resources. These include:

- a voluntary International Code of Conduct for Plant Germplasm Collecting and Transfer;
- a draft Code of Conduct on Plant Biotechnologies;
- international agreements on genebanks;
- the World Information and Early Warning System on Plant Genetic Resources, which facilitates information and technology exchanges;
- international networks of *ex situ* collections and *in situ* conservation areas, with complementary basic agreements on genebanks;
- a periodic publication on the State of the World's Plant Genetic Resources, to assist the CPGR to fulfil its monitoring responsibilities;
- a Global Plan of Action on Plant Genetic Resources to facilitate the CPGR's coordination role; and
- an International Fund on Plant Genetic Resources to implement Farmers' Rights. (FAO 1995, Item 5)

Several of these agreements and projects will be discussed in greater detail, below.

The Global System covers the conservation (*ex situ* and *in situ*, including on-farm) and utilization of plant genetic resources (genes, genotypes and genepools) at molecular, population, species and agro-ecosystem level. (FAO 1995, Item 5) 144 countries are now formally part of the system, having either adhered to the Undertaking or joined the CPGR, or both.

It may be noted that, unlike the Biodiversity Convention, all the FAO activities are limited to plant genetic resources, specifically those of interest to food or agriculture. However, in November 1994, a proposal was made that the CPGR expand its scope to encompass farm animals, forestry and fisheries, beginning with the inclusion of farm animal genetic resources. This was considered further at the Sixth Session of the CPGR, which took place June 19-30, 1995, but as of this writing it is unknown whether any consensus was reached on this issue. (FAO 1995, Item 5)

3.4 International Code of Conduct for Plant Germplasm Collecting and Transfer

In November, 1993, the FAO Conference adopted a Code of Conduct⁴⁶ for procedures to request and/or issue licences for collection of plant germplasm. The Code is a voluntary one, which sets minimal standards that could be acceptable to every country. It was prepared to fill in gaps, consistent with the Biodiversity Convention and pending revision of the 1983 Undertaking. Notably, reflecting the terms of the Biodiversity Convention, it is based on the principle of *national sovereignty* over plant genetic resources.

The stated objectives of the Code include: promoting the conservation, collection and use of plant genetic resources in ways that respect the environment "and local traditions and cultures"; fostering direct participation of farmers, scientists and organizations in the source country; avoiding genetic erosion; promoting the sharing of benefits derived from plant genetic resources between the donors and users of germplasm, related information and technologies; and bringing recognition to the rights and needs of local communities and farmers and those who manage wild and cultivated plant genetic resources, in particular promoting mechanisms to facilitate compensation of local communities and farmers for their contribution to the conservation and development of plant genetic resources.

In essence, it encourages states to establish systems for the issuance of *permits* to collectors, and sets *standards of conduct* for collectors to observe before, during and after the collecting process. It asks users of the germplasm to consider providing some form of *compensation* to local communities, farmers and the source country in the form of facilitated access to new, improved varieties and other products on "mutually agreed terms", research support, training, transfer of technology for the conservation and use of the resources, scientific and technical information obtained from the germplasm, and other "appropriate" support.

3.5 Draft Code of Conduct on Biotechnology

Reflecting the close connection between biotechnology and plant genetic resources, the Fourth Session of the CPGR requested that a Code of Conduct on Biotechnology be prepared, with respect to its effects on the conservation and use of plant genetic resources. A first draft was presented in 1993.

⁴⁶ A copy of this code is included as Appendix 2 in the companion study to this one, "Intellectual Property Rights, Biotechnology, and the Protection of Biodiversity: Literature Review" by Howard Mann.

Most of the Code is currently under revision.⁴⁷ One of the four chapters in the draft addresses the promotion of biotechnology for the conservation and sustainable utilization of plant genetic resources. Its provisions try to maximize the positive effects on biotechnology while minimizing its potential adverse ones. They also *promote access* to relevant biotechnologies and to the plant genetic resources. There is another chapter on biosafety, which will be considered as input to the work on-going under the auspices of the Conference of the Parties to the Biodiversity Convention on the subject, with participation by the FAO.

3.6 International Agreements on Genebanks

Historically, most of the *ex situ* germplasm collections assembled from the 1950's through the 1980's were maintained and managed outside the FAO, first by International Agricultural Research Centres (IARCs) established with US funding in various developing countries, and then coordinated by the Consultative Group for International Agricultural Research (CGIAR).

In 1974, it was decided to establish a coordinated program of collection and conservation of plant genetic resources, to ensure that essential raw materials would not be lost to genetic erosion. As a compromise between the twin contenders of the FAO and the CGIAR, it was decided to create the International Board for Plant Genetic Resources (IBPGR), which would be located at the FAO headquarters, but operate as a CGIAR institution.

The IBPGR established a network of national and international centres for germplasm collection, so that by the mid-1980's, it reported that it had 600 scientists working in more than 100 countries, with 177 base germplasm collections in 43 genebanks. (Lacy, 1995) By the late 1980's, however, most of the stored germplasm was kept in collections located in the developed nations; less than 15% was located in developing countries. This led to a series of conflicts between developed and developing countries. In an attempt to resolve some of this controversy, in 1992 the IBPGR was replaced by the International Plant Genetic Resources Institute (IPGRI).

IPGRI endorsed a new strategic plan with four principal objectives: to assist countries, especially developing ones, to assess and meet their conservation needs for plant genetic resources, and strengthen their links to users; to build international collaboration mainly through the encouragement of networks based on crop and agricultural criteria; to develop and promote strategies for the conservation of the resources; and to provide an information service.

As part of the Global System, there is now movement to consolidate jurisdiction for the various interrelated issues on plant genetic resources under one single umbrella, the FAO, with the technical assistance of IPGRI. This had been anticipated by the 1983 Undertaking, but never implemented. The Undertaking had stated that the network of national, regional and international

⁴⁷ The Tenth Session of the Working Group decided against presenting the draft at the Sixth Session of the CPGR in June, 1995.

centres, under the FAO's auspices, would "[assume] the responsibility to hold, *for the benefit of the international community and on the principle of unrestricted exchange*, base or active collections of the plant genetic resources of particular plant species." (Article 7.1)

Article 7.2 went on to state that, "The centre concerned will, whenever requested by FAO, make material in the base collection available to participants in the Undertaking, for purposes of scientific research, plant breeding or genetic resource conservation, free of charge, on the basis of mutual exchange, or on mutually agreed terms."

At its Fourth Session, the CPGR agreed on three model basic agreements to begin negotiations with governments and international institutions. Under the agreements, the government or institution would place the designated germplasm of the collection in the International Network under the auspices or jurisdiction of the FAO, and make the germplasm available without restriction for purposes of scientific research, plant breeding or conservation. Thirty-two countries have expressed their willingness to make their genebanks part of the International Network.⁴⁸

The FAO, CGIAR and IARCs are now considering the issue of collections held by the IARCs. Since 1990, the Centres have taken the position that they are not the owners of the germplasm -- which was collected through international collaborations -- but rather, that they hold them in trust on behalf of the beneficiaries. The CGIAR has variously identified the beneficiaries as humanity, developing countries, their farming communities, and research workers.

In 1993, the Centres offered to place their base and active collections in the International Network, under the FAO. The Fifth Session of the CPGR considered a draft agreement presented by IPGRI, on behalf of the IARCs, to effect this transition; subject to clarifying the "ownership" of the resources held, and the implications of the "trusteeship" concept, this was positively received.

The CPGR noted that the IARCs imposed obligations on its Centres to conserve the material to the highest technical standards; to duplicate it (for safety reasons); to make it available without restrictions; and not to seek any intellectual property rights over it. This last obligation includes, where necessary, the use of material transfer agreements to prevent third parties subsequently claiming intellectual property rights.

In October, 1994, twelve centres of the CGIAR signed agreements with the FAO placing designated *ex situ* collections stored in their genebanks under the FAO. Negotiations are continuing with countries and other institutions to develop and expand this process. (FAO 1995, Item 5; FAO 1995, Item 8(b))

⁴⁸ Argentina, Bangladesh, Chile, Costa Rica, Czech Republic, Denmark, Ethiopia, Finland, France, Germany, Indonesia, India, Italy, Japan, Iraq, Madagascar, Morocco, Netherlands, Norway, Pakistan, Philippines, Russia, Senegal, Spain, Sweden, Switzerland, Syria, Togo, Tunisia, United Kingdom, Uruguay and Yemen.

3.7 Revision of the 1983 International Undertaking

3.7.1 Background

As discussed earlier, Agenda 21 called for the strengthening of the FAO Global System of Plant Genetic Resources, and its adjustment in accordance with the Biodiversity Convention, as well as the realization of Farmers' Rights. The Conference for the Adoption of the Agreed Text of the Convention on Biological Diversity passed a complementary resolution that noted that existing *ex situ* collections and Farmers' Rights were issues not addressed by the Biodiversity Convention, and asked the FAO to use the Global System for Plant Genetic Resources to search for solutions to these issues.

In response, the FAO Conference adopted Resolution 7/93 in November, 1993, asking the Director-General for a forum for negotiations among governments for:

- the adaptation of the 1983 International Undertaking in harmony with the Biodiversity Convention;
- consideration of the issue of access on mutually agreed terms to plant genetic resources, including *ex situ* collections not addressed by the Convention; and
- the issue of Farmers' Rights.

The first negotiating session for this Revision of the 1983 Undertaking took place June 19-30, 1995. This was immediately preceded by the Tenth Session of the Working Group of the CPGR, which met in May, 1995, and then immediately reported at the June meeting of the CPGR. The writers of this study have only been able to obtain limited documentation about these meetings. In general, we understand that no consensus has yet emerged on the issues under discussion.

A number of documents were prepared in preparation for the discussions, including several background documents on the technical, legal and economic issues of importance to these issues. The studies were premised on the principle that plant genetic resources for food and agriculture are inherently different from other plant genetic resources, and therefore distinct solutions may need to be found to ensure their conservation, development and availability, and the fair and equitable sharing of benefits derived from their use. Some of the differences highlighted were the following:

- Plant genetic resources for food and agriculture are essentially man-made, ie, biological diversity developed and consciously selected continuously by farmers since the origins of agriculture over 10,000 years ago. Recently, scientific plant breeders have built upon this inheritance. Much of the genetic diversity of cultivated plants can only survive through continued human conservation and maintenance.

- These plant genetic resources are not randomly distributed across the globe, but rather concentrated in "centres of origin and diversity" of cultivated plants and their wild relatives, which are largely located in the tropical and sub-tropical areas.
- Because of the diffusion of agriculture all over the world over the last 10,000 years, and because of the association of major crops with the spread of civilizations, many crop genes, genotypes and populations have spread and continue to develop all over the globe. Moreover, plant genetic resources for food and agriculture have been systematically and freely collected and exchanged for over 200 years, and a large proportion incorporated in *ex situ* collections, established before the entry into force of the Biodiversity Convention (and therefore falling outside its scope).
- There is much greater inter-dependence among countries for plant genetic resources for food and agriculture than for any other kind of biodiversity. At the regional level and for major crops the average inter-dependency has been estimated to exceed 70%; at the national level, it may be estimated that every country depends on genetic resources originating outside its borders, for more than 90% of its major crops. Continued agricultural progress implies the need for continued access to the global stock of plant genetic resources for food and agriculture. No region can afford to be isolated, or isolate itself, from the germplasm of other parts of the world. (FAO 1995, Item 8(c))

At the Tenth Session of the Working Group of the CPGR, held in May, 1995 in preparation for the June meeting, the delegates discussed whether the revised Undertaking should comprise both *in situ* and *ex situ* conservation, and sustainable utilization. It was suggested that the revised Undertaking should also include the objectives of the Biodiversity Convention, adapted for plant genetic resources for food and agriculture and Farmers' Rights, and other objectives intended to enhance food security.

There was discussion, but no consensus, of the appropriate scope of the Undertaking. The delegates discussed whether it should be limited to resources acquired prior to the entry into force of the Biodiversity Convention, or to those resources acquired subsequently, or encompass both. They also discussed whether it should encompass all plant genetic resources for food and agriculture (e.g., whether it should include forest genetic resources), or be more limited. One suggested option⁴⁹ was not to exclude any group of plants that were actually or potentially of relevance to food and agriculture, but to add a list of mutually agreed species to which specific provisions of the Undertaking would apply, particularly in relation to access to and the distribution of benefits. This list would be an appendix to the revised Undertaking, that could be updated periodically. This option was described as receiving "fairly broad acceptance" among the delegates, subject to the

⁴⁹ Other options suggested were: to keep the present formula, to cover "plant genetic resources of economic and/or social interest, particularly for agriculture"; and to restrict the scope of the Undertaking to genetic resources of cultivated plants, their wild relatives and wild food crops which are harvested, specifically excluding forestry genetic resources."

concern expressed that incorporation of such a list could lead to greater attention being paid to major crops, to the detriment of minor or local ones.

3.7.2 Conditions of Access to Plant Genetic Resources

All existing collections which are located outside of the country of origin (defined in the Biodiversity Convention as the "country which possesses those genetic resources *in situ* conditions") and which existed at the time the Biodiversity Convention entered into force (December 1993) are, by definition, collections that were not acquired in accordance with the terms of the Convention, and provisions for access to these collections are excluded under Article 15.3 of the Convention.

Both in terms of their size germplasm collections have been established in about 130 countries, with worldwide holdings of about 4.4 million accessions -- and in terms of their importance -- for agricultural crops, these collections have served as the primary means of conservation, readily accessible to breeders and scientists -- it is important to establish internationally accepted conditions of *access*. The FAO background report noted that, "the actual and potential value of these collections, for the crops concerned, is generally considered to be higher than that of the diversity not yet collected. It was not by chance that this germplasm was selected, given priority and attention, and funds made available for collection and storage, and, in many cases, characterization, documentation and exchange." (FAO 1995, Item 8(c), ¶ 23.)

The question of *ownership* of the tangible material in the collections is also unsettled. The material was generally collected through international cooperation, often taken from developing countries (the main areas of diversity of cultivated species) and stored in genebanks located mainly in industrialized countries. Many countries raised the question whether this material belonged to the country where it was collected, the country/institution where it was stored, or alternatively to humankind.

The FAO concluded in a 1987 study that material stored in government or public genebanks -- notwithstanding where it had been obtained -- was considered to be vested in the states where those genebanks were located. However, with respect to material stored in the IARCs, the legal position was not so clear, due to a lack of explicit provisions in the available charters and other legal documentation under which the Centres had been established. The IARCs have since established their policy on this issue, namely that the material is held "in trust" for the international community.

In 1993, the CPGR noted that there are fundamentally three possible interpretations of the legal status of these collections, considered in the context of the regime established by the Biodiversity Convention:

1. that these genetic resources were outside the Convention, and, since most of them were collected on the general understanding that plant genetic resources were the heritage of humankind, these resources should continue to be freely available, with global compensatory mechanism;

2. that these genetic resources were outside the Convention, and therefore that the host country could legislate on ownership and conditions of access;⁵⁰ and
3. that, since the Parties to the Convention can provide only those genetic resources originating in their own countries, or acquired under the terms of the Convention, that the permission of the country of origin is required for the release of genetic resources from pre-existing collections. It was noted, however, that, in many cases, countries of origin cannot be identified, and that the collection are widely dispersed (quoted in FAO 1995, Item 8(b), ¶ 31.)

The CPGR suggested several options, not necessarily mutually exclusive, that could be explored within the framework of the Global System:

1. the facilitation of bilateral agreements between countries of origin, when they can be identified, and countries holding *ex situ* collections, for the sharing of the benefits;
2. the establishment of agreements between FAO and the owners of genebanks, including provisions on access, along the lines of the "model basic agreements," as agreed at the Fourth Session of the Commission; and
3. facilitation of a comprehensive multilateral agreement concerning access to *ex situ* collections, including mechanisms to compensate countries of origin, possibly in the context of the proposed revision of the Undertaking. It should be noted that where countries of origin cannot be identified, compensation could be provided to developing countries collectively. (FAO 1995, Item 8(b), ¶ 32.)

The Tenth Session of the Working Group of the CPGR in May, 1995 discussed how the Undertaking should treat material acquired before and after the entry into force of the Biodiversity Convention. It was noted that there are practical difficulties in trying to distinguish between plant genetic resources acquired before the Biodiversity Convention and those acquired after, as well as practical difficulties in trying to identify the place of origin of the former. Delegates stressed the importance of national sovereignty, and the need to take account of national legislation. At the same time, it was noted that there is a difference between sovereignty and ownership: a state can be sovereign over resources which may themselves be privately owned.

⁵⁰ It may be anticipated that this could perpetuate the concern expressed by developing countries that having given up their genetic resources to the heritage of humankind in the collection process, they are now denied access to those resources taken from their own country.

No consensus emerged during the discussions of the Working Group. Consideration was given to drafting the revised Undertaking so as to provide for access to previously existing collections on the basis of free access and the implementation of Farmers' Rights on mutually agreed terms in a multilateral framework, while access to later-acquired material would be negotiated by the parties on mutually agreed terms. Some delegations wished to be able to apply a common multilateral regime, at least to those species or gene pools of relevance to food security, and those for which there is strong interdependence among countries.

Notably, reference was made to Article 16 of the Biodiversity Convention, on access to technology, and the need for this to be linked to plant genetic resources access. The Report of the Chairman of the Working Group notes that, "It was recognized that access to plant genetic resources, biotechnology and the funds should be linked, in both multilateral agreements and bilateral agreements." Unfortunately, we have not yet been able to learn more about these discussions.

3.7.3 The Issue of Farmers' Rights

The idea of farmers' rights originated in debates within the FAO on the asymmetric treatment afforded donors of technology and donors of germplasm. Plant breeders' rights or other intellectual property rights protect and compensate breeders for applying technology to what is usually farmers' germplasm. However, no system for compensating the farmers was in place. As a result of these debates, it was decided to recognize both plant breeders' rights and farmers' rights simultaneously in resolutions in 1989 and 1991.

The resolutions recognize "the enormous contribution that farmers of all regions have made to the conservation and development of plant genetic resources, which constitute the basis for plant production throughout the world, and which form the basis for the concept of Farmers' Rights." (Resolution 4/89)

Farmers' rights are described as: "rights arising from the past, present and future contribution of farmers in conserving, improving and making available plant genetic resources, particularly those in the centres of origin/diversity. These rights are vested in the International Community, as trustees for present and future generations of farmers, for the purpose of ensuring full benefits of farmers and supporting the continuation of their contributions." (Resolution 5/89) As will be seen below, this description -- which is very vague, and does not really state what precisely the rights are -- has formed the foundation of both international understanding of the concept and how to address it (the international trusteeship). For example, as will be seen, this description is used verbatim in a proposal currently before the Andean Pact countries.

Implementation of farmers' rights is seen as fulfilling a dual role:

- ensuring that farmers, farming communities and their countries receive a just share of the benefits derived from plant genetic resources that they developed, maintained and made available; and

- provide incentives and means for the conservation and further development of these resources by farmers and through international cooperation between farmers, breeders and the scientific communities.

The impetus for enshrining farmers' rights in national and international legal mechanisms has significantly increased in recent years as a result of the TRIPs accord on intellectual property rights under the WTO/GATT. The TRIPs chapter obligates parties to protect the rights of commercial breeders and biotechnologists, and their companies, and to ensure that they can claim and receive royalties on new seeds and other related products through patents, plant breeders' rights or *sui generis* systems.

As will be seen below, some developing countries are considering including a national mechanism for farmers' rights as they develop a *sui generis* system in compliance with TRIPs. In addition, the FAO notes that "to be fully successful, the implementation of Farmers' Rights needs international action. This is because, in every country, most of the germplasm used in agriculture comes from other countries. According to recent studies, any region of the world is dependent on genetic material which originated in other regions for over 50% of its basic food production, and for several regions of the world, such dependency is close to 100%." (FAO, 1995, Item 8(b))

The Governing Bodies of the FAO decided to establish an International Fund for Plant Genetic Resources, to support plant genetic conservation, management and utilization programs, particularly within developing countries and countries with important plant genetic resources. Special priority would be placed on intensified educational programs for biotechnology specialists, and strengthening the capabilities of developing countries in genetic resource conservation and management, as well as the improvement of plant breeding and seed production. (Resolution 4/89)

It was decided in 1993 to ascertain and quantify the technical and financial needs to attain these objectives, through a country-driven process to identify the necessary activities, projects and programs. A Trust Fund project has been established in the FAO -- the International Conference and Program on Plant Genetic Resources -- which is proceeding with this.

Some of the outstanding questions include:

- whether the funding should be voluntary or mandatory;
- the linkage between the financial responsibilities and the benefits derived from the use of plant genetic resources;
- who should bear the financial responsibilities countries, users, or consumers;
- how to estimate the relative needs and entitlements of beneficiaries;

- how farmers and local communities would benefit from the funding;
- whether the Fund should be separate, part of a wider mechanism (eg, a window of the funding mechanism for the Biodiversity Convention), or a combination of the two; and
- issues relating to the administration and operation of the Fund, including possible types and degrees of decentralization.

The issue of Farmers' Rights was discussed at the Tenth Session of the Working Group for the CPGR. The need for a legal framework for the exercise of these rights was noted, which could arise in legislation or at the level of "international law".

The relationship between Farmers' Rights and plant breeders' rights was discussed, with many delegations considering the two should be developed "on an equal footing."

There was agreement on the need to develop the International Fund on Plant Genetic Resources, to make Farmers' Rights effective, and the delegations discussed proposals on the purposes and objectives to which the Fund could contribute. Some delegations suggested that implementation of Farmers' Rights should not be limited to the Fund, but should also include things like: the traditional right of farmers and their communities to keep, use, exchange, share and market their seeds and plant reproductive matter, including the "farmer's privilege"; access by farmers to new technologies and other research achievements; protecting local technologies, traditional cropping practices and other informal innovative systems; and the rights of communities as custodians of indigenous knowledge and of their own plant genetic resources.

The report observed that, "Many delegations considered that Farmers' Rights should be developed through a *sui generis* system (whether or not based on intellectual property rights) at the national and international levels."

It was pointed out during the meeting that several concepts were being addressed, and that to avoid confusion, these different "operational dimensions" of Farmers' Rights should be dealt with separately, perhaps in separate articles of the Revised Undertaking. Three articles were proposed:

- 1 restating and balancing the concept of Farmers' Rights against that of plant breeders' rights; including the acknowledgement of the right to the "farmers' privilege", namely the right to continue the traditional practice of re-using on their own holdings the seeds they harvest themselves;
2. linking Farmers' Rights to the funding mechanism, which would provide both compensation and the desired incentives for farmers' conservation and development activities, and also lay the foundation for just and equitable sharing of the benefits

derived from plant genetic resources, with a possible reference to the Global Plan of Action; and

3. establishing the rights of traditional farmers and communities in the national context, as custodians of indigenous knowledge and plant genetic resources (in line with Article 8(j) of the Biodiversity Convention).

The delegates discussed whether Farmers' Rights should be developed "on an equal footing" with plant breeders' rights. The concept of "added value" inherent in Farmers' Rights was emphasized, which justified their collective character, as was the difficulty of likening them to plant breeders' rights -- although it was also suggested that the two should be considered to be complementary, not opposed, as farmers could be considered beneficiaries of the work of plant breeders.

3.7.4 Proposed Revisions to the Global Plan of Action

One of the issues under consideration is a revised structure for the Global Plan of Action. This is scheduled for discussion at the Fourth International Technical Conference on Plant Genetic Resources, to take place in Leipzig, Germany, in June 1996.

The current proposal is to reorganize the Global Plan of Action around a *declaration*, which would begin with the principle of national sovereignty over biological resources, and confirm "our common and individual responsibilities towards this heritage." The draft declaration simultaneously acknowledges both "the roles played by generations of farmers, in particular women farmers, farming communities and indigenous populations" and "breeders and scientists" in conserving and improving plant genetic resources.

The draft declaration also recognizes the interdependence of countries and peoples regarding plant genetic resources for food and agriculture, and the need to facilitate "access to and the sharing of both genetic resources and technologies." It recognizes the need to strengthen national capacities, "especially in developing countries" to address problems of conservation and utilization. As written, the draft would place a priority on mobilizing financial resources for these activities; however, the question of funding is to be addressed separately, so that these provisions are placed in parentheses.

With these principles, the reorganized Global Plan of Action would provide recommendations of policies and priority activities. The overriding purpose is to ensure that the Plan is "action-oriented", that is, implement a strategy, with clear aims and principles, to guide international cooperation on plant genetic resources for food and agriculture.

3.8 The Keystone International Dialogue and SAREC Consultation

Mention should be made of the Keystone International Dialogue Series on Plant Genetic Resources. Initiated in 1988, it brought together a wide range of interests to participate in a structured, off-the-record, consensus-building dialogue to promote a strong international commitment to conserving plant genetic resources. It included participants from international and intergovernmental organizations, national government organizations, non-governmental organizations, corporations and research institutes, from both developing and developed nations.

In its third and final report, in 1991, the participants set out a Global Initiative for the Security and Sustainable Use of Plant Genetic Resources, calling for the immediate joint efforts and involvement of everyone involved and affected, including contributors of germplasm, information, technology, funds and systems of innovation. The report identified a number of activities required, as they stated, urgently, to combat the threat of genetic erosion. These included *in situ* and *ex situ* conservation measures, on-farm conservation and utilization, monitoring and early warning of specific genetic erosion, development of techniques for sustainable advances in agricultural productivity, and research, training and public education. (Keystone Report, 1991)

With respect to farmers' rights, the second Keystone Dialogue agreed that "the best way of recognizing farmers' rights would be a mandatory fund," and that "there should be a compulsory funding mechanism." The third and final report included a fund for plant genetic resources as part of its Global Initiative.

The Government of Sweden through SAREC, the Swedish Agency for Research Cooperation with Developing Countries, recently (March, 1995) convened an international "consultation" of experts, to follow up on the Keystone recommendations "post-UNCED". The group concluded that a legally binding, multilateral agreement is needed, to strengthen national and international efforts for the conservation and sustainable use of plant genetic resources for food and agriculture, and provide for the equitable sharing of the benefits from their exploitation. The agreement may cover both *in situ*, including on-farm, and *ex situ* resources, and their use, including direct use, use in traditional plant breeding and biotechnology. The participants anticipated that there may be some circumstances in which countries would prefer to manage some of these resources outside the multilateral agreement, and proposed alternatives to address this, including use of an annex, or separate bilateral agreements for resources excluded from the agreement.

The benefits that would accrue from participation in the multilateral agreement would be access to samples of plant genetic resources identified in an annex to the agreement, financial resources, information and knowledge, technology through increased international cooperation, and training programs. The group agreed that these benefits should be shared equitably. They identified several issues for future consideration, including: exploring possibilities for *quid-pro-quo* arrangements, for example, through the use of material transfer agreements and other contractual agreements; how to engage the private sector and local communities in the full spectrum of benefit sharing; how to address the more intangible social and environmental benefits of these plant genetic resources, such as employment, ecological services, etc.; and whether multilaterally agreed terms

of access to samples of genetic resources can be developed in the context of the revised FAO Undertaking, including what trade-offs would facilitate open, unpaid access in the context of generalized arrangements for benefit sharing.

With respect to property rights, the group agreed that the aim is to ensure that property rights are supportive of and do not run counter to the objectives of the Biodiversity Convention, the revised Undertaking, and the efforts to establish a multilateral system. Issues identified for future consideration included whether the current system of intellectual property rights meets this aim, and whether *sui generis* systems can be designed in conformity with both the Biodiversity Convention and the WTO to adequately address community innovation, to ensure it benefits the local community, farmer and indigenous innovators, and that it conforms with the multilateral agreement.

Finally, the group discussed the use of a funding mechanism, including the best way to set priorities for funding, especially to focus on support for the activities of farmers, local communities and indigenous people; whether it should be used to pay "royalties" for the use of material protected by intellectual property rights; whether contributions should be voluntary or mandatory; and questions about the linkage between financial contributions and benefits obtained from the use of plant genetic resources.

Institutionally, it was proposed that the multilateral agreement have its own intergovernmental governing body, that would report to the Conference of the Parties of the Biodiversity Convention. Representatives of farming communities, non-governmental organizations, international organizations and the private sector could be encouraged to participate as observers. It would be assisted by a secretariat and an intergovernmental open-ended scientific and technical advisory body (STAG). FAO's role with respect to the secretariat, and IPGRI's role with respect to STAG, would have to be explored.

It may be noted that, just as the Keystone recommendations proved influential, so the SAREC report is being afforded wide dissemination. A delegation submitted the report at the Tenth Session of the Working Group of the CPGR in May, 1995, and this was noted in the Chairman's report.

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4.0 SURVEY OF COMPARATIVE APPROACHES TO THE IPR/BIODIVERSITY LINKAGE

As is clear from the preceding discussion, a shift of thinking has occurred about genetic resources: once the "common heritage of humankind," increasingly now they are a "common concern" of all, but (with the exception of prior *ex situ* collections, whose status is still to be decided) left to be governed by the state where they are located.

This part will examine legislative and other initiatives that are taking place in a number of countries located in South and Central America, Africa, and Asia, to address these issues.

Summary⁵¹

A number of interesting initiatives are underway in the countries surveyed. Several of these initiatives -- notably those in the Andean Pact countries, the Philippines, The Gambia and Cameroon -- were cited in a recent report by the Secretariat to the Conference of the Parties to the Convention on Biological Diversity (Biodiversity Convention Secretariat Report, 1995), and may therefore be influential in the development of other national, and perhaps multilateral, policies and legislation governing access to genetic resources.

The Andean Pact countries (Bolivia, Colombia, Ecuador, Peru and Venezuela) have been working on a Common Regime on Access to Biogenetic Resources, that would reflect the implement the Biodiversity Convention. The draft decision prepared to effect this common regime starts from the premise that states have sovereign rights over their natural resources, and the authority to determine questions of access to those resources. All states would declare all genetic resources to be part of the national patrimony.

All access to genetic resources, for scientific, commercial or industrial purposes, is to be regulated by the member-states on the basis of prior informed consent and mutually agreed terms. The source country is a mandatory party to any decision on access, even where the requested access is to a resource on private property.

The draft decision adopts the concept of Farmers' Rights, and the vesting of those rights in the international community as trustee.

⁵¹ This summary highlights the developments in the identified countries with respect to regulation of access to genetic resources. Related developments, including with respect to intellectual property protection such as plant breeders' rights and patent rights for intangible information in unique genetic information in the genetic resources, are discussed in the body of the section for each country but not highlighted here.

The proposals leading up to preparation of the draft decision recommended making access to genetic resources subject to governmental authorization, which would consist either of a valid Certificate of Origin (for in situ resources), or a Material Transfer Agreement (for ex situ resources). Every subsequent transfer of the accessed material would have to be accompanied by this authorization. This system would link the access requirements and intellectual property regimes: patents and other intellectual property rights would only be granted upon presentation of the Certificate as proof of prior informed consent.

The draft decision also recognizes rights of indigenous and local communities over their knowledge, innovations and practices. The issue of the extent to which such rights should be recognized, was contentious during the development of the draft decision. One of the proposals leading up to preparation of the draft decision recommended extending intellectual property rights (not just tangible property rights) to biodiverse genetic resources whose value resided in the fact of their conservation, rather than in any novelty.

Special conditions are to be established for access to genetic resources of indigenous and local communities, to enable these communities to secure compensation. The draft requires that those seeking access to indigenous knowledge, innovations and practices must conclude an agreement directly with the indigenous peoples, as a condition precedent to granting rights of access to associated genetic resources.

*The **Costa Rican** experience has had perhaps the most influence internationally of any single country. The strategy employed was multi-faceted, involving: the establishment of a large National System of Conservation Areas; the creation of a National Institute of Biodiversity (INBio -- Instituto Nacional de Biodiversidad) to conduct an inventory of the country's natural resources, and to work with national and international institutions towards appropriate economic and intellectual use of those resources; establishment of a strong legal framework regulating access to and control of biological samples; and implementation of social policies to create a skilled and educated workforce.*

The study reviews each of these aspects of the Costa Rican strategy, with particular focus on the legal framework and the terms of INBio's access agreements with commercial and research organizations, seeking access to Costa Rican genetic resources. Under the Wildlife Conservation Law, the State has the exclusive right to commercialization of genetic resources, which are declared to be part of the national patrimony. INBio is authorized by the government to enter into its access agreements, while a significant portion of revenues received under the agreements is transferred to the government for conservation purposes.

The standard INBio access (or bioprospecting) contract includes terms for up-front payments, as well as royalty payments; technology transfer; and regulation of the ownership of both the tangible resource specimens, and the intangible rights in the information in or obtained from the specimen. These contracts have laid the framework for virtually all subsequent bioprospecting agreements, wherever located and whomever between.

Mexico recently established CONABIO, the National Commission for the Knowledge and Use of Biodiversity. CONABIO's role is primarily one of promotion and coordination; it does not itself engage in the collection of specimens (unlike INBio). It is in the process of developing a policy framework to govern access to Mexico's genetic resources. It recently prepared draft bilateral agreements with Australia, Cuba, Costa Rica and the United States, for cooperative activities in developing, accessing, analyzing, managing and communicating biological data information.

Cameroon recently established a legislative framework for integrated management, conservation and sustainable use of forests, fauna and fisheries. The legislation provides that genetic resources belong to the state, and prohibits anyone exploiting the resources for scientific, commercial or cultural purposes, without authorization. The law also requires payment of royalties to the state, where financial or economic benefits result from the use of Cameroonian genetic resources.

A study was recently conducted of the regulatory context in Cameroon governing bioprospecting, and recommendations were made for improvement. This study, and the recommendations, are detailed in this survey.

The Gambia recently enacted legislation authorizing the competent national authority to regulate, including prohibiting, trade or traffic in any component of biological diversity. The genetic resources are declared to be an essential part of the natural wealth of resources of the people The Gambia. The implementing regulations and guidelines are to regulate the export of germplasm, the sharing of benefits derived from Gambian germplasm, and fees for access to the germplasm.

In *India*, there is currently no single, coordinated legislative framework governing access to and use of genetic resources. A proposal for a system of regulation of access to genetic resources is in the preliminary stages of preparation, but no legislation has been introduced and the substance of the proposal remains confidential. This study reviews the controversial (related) amendments to Indian intellectual property laws, and also a proposal by the Third World Network for an alternative intellectual property regime to protect indigenous and local communities' knowledge and resources.

The Philippines recently issued an Executive Order prescribing guidelines for scientific and commercial bioprospecting. The Order reiterates Philippine constitutional law that wildlife, including flora and fauna, are owned by the State, which has full control and supervision over its disposition, development and utilization. It establishes an Inter-Agency Committee on Biological Resources, which would include representatives of different government departments, academics, non-governmental organization representatives, and representatives of indigenous communities and organizations. This Committee would consider bioprospecting applications, and review the Philippine legislative framework. (Among other things, the Committee is specifically directed to consider new laws on intellectual property rights.)

All bioprospecting of biological and genetic resources must be pursuant to a Research Agreement concluded with the government. This can be either a Commercial Research Agreement or an Academic Research Agreement. The Order stipulates minimum terms for these agreements, and these are detailed in the study. Among others, the terms must regulate the quantity of specimens that

may be removed, and require continued access for Philippine government entities and citizens to both those tangible specimens and to the intangible data, where the specimens are removed from the country. Provision must be made for the payment of royalties, if commercial use is derived from the resource, and possibly other forms of compensation provided as well.

Notably, the Order requires the prior informed consent of local and indigenous communities, before bioprospecting will be permitted on "ancestral lands and domains" of these communities. The Order is explicit that royalty payments must be made to these communities.

*In **Indonesia**, the current regulation of access to genetic resources is found in the Rules and Procedures Governing Permission from the Government of Indonesia for Foreign Researchers to Conduct Research in Indonesia, issued by the Indonesian Institute of Science (the so-called "LIPI Rules"). While these remain officially in effect (and their terms are detailed below), in fact we are advised that access is usually determined under the terms of access agreements, for example concluded with universities or the United States National Cancer Institute (NCI). These terms are also discussed below.*

***Australia** is in a highly unusual position, as both a supplier and user of genetic resources. This perspective presents an opportunity for Australia to play a lead role in shaping international practice.*

Responsibility for environmental matters is divided among the Commonwealth, States and Territories. Much of the policy, legislative and administrative framework for the management of living and non-living resources, falls within State and Territorial authority. The study reviews the existing legislation in the States and Territories regulating access to Australian genetic resources. For example, the Queensland government is in the process of preparing draft legislation vesting ownership of the genetic material of Queensland wildlife in the state, and regulating access through a permit system, with financial agreements regarding the use of genetic materials.

Australia is currently considering using a Commonwealth-State consultative process to arrive at a national approach for managing access to Australian genetic resources, but this process is not expected to be completed before early 1996.

There have been several studies of appropriate ways to regulate access to Australian genetic resources, and these are described in detail below. The studies note the need to consider the use and ownership of the traditional knowledge, innovations and practices of indigenous and local communities, including benefit sharing mechanisms, and the issue of the ownership of flora and fauna on indigenous peoples' lands and the use of appropriate intellectual property mechanisms. One study recommended the establishment of property rights that relate to the development and sale of genetic products, and establish intellectual property rights derived from knowledge of genetic diversity, especially of indigenous peoples.

One report recommended the adoption of three basic principles to protect Australian interests as a biodiverse nation: (1) that Australia control access to indigenous biological resources in accordance with the terms of the Biodiversity Convention; (2) that international access be granted on terms that recognize Australia's rights of ownership in the genetic material, rights to involvement in research on the material, and rights to fair and equitable return on, and proportionate ownership of, commercial products developed from Australian biological resources; and (3) that the governments reserve the right to set fees, royalties or other charges relating to the grant of access, and to receive all reports of research relating to the commercial potential of those resources.

In New Zealand, the issue of the role of intellectual property rights in establishing terms of access to or use of genetic resources, is still in the early stages of discussion. The Government placed a moratorium on the issuance of permits to collect genetic material for commercial purposes, and is in the process of identifying stakeholders to assist in preparation of a new policy on the issue.

A major issue in New Zealand has concerned the cultural and intellectual property of indigenous peoples, particularly with respect to traditional knowledge of the Māori. Recent developments on this issue, including the 1993 Mataatua Declaration, the Treaty of Waitangi claim of Māori ownership of indigenous flora and fauna, and proposed amendments to New Zealand intellectual property legislation, are detailed below. For example, the Treaty of Waitangi claim, scheduled for pre-judicial hearing later this year, will address Māori claims that the New Zealand government breached the Treaty by allowing the patenting of inventions, and the granting of plant breeders' rights (called plant variety rights), in relation to indigenous flora.

*Finally, a series of **regional roundtables** were organized in 1994, bringing together leading individuals in the field from government, non-governmental organizations, indigenous peoples' groups, regional institutions, international institutions, and the scientific and academic communities. The ideas presented and discussed at these roundtables are discussed below.*

Latin America⁵²

4.1 The Andean Pact: Venezuela, Colombia, Ecuador, Peru and Bolivia

4.1.1 Background

Resources

The Andean region has been described as the "cradle of agriculture" -- the first demonstrable uses of plants for food in the Andean region date back 9,000 to 10,000 years ago. Among other crops, this region contributed the potato and landraces of maize to Europe and elsewhere. However while numerous Andean plants were disseminated to Spain and elsewhere, a large number of others were rejected by the Europeans. Over time, many of the native crops were replaced by introduced species, and the wide variety of native crops were consigned only to continued cultivation on small farms, and in poor or isolated Indian communities. This isolated cultivation resulted in the region's great plant genetic diversity -- most of which today remains unknown, uncollected and unstudied. (Castillo, 1995)

The great Russian plant collector, N.I. Vavilov, classified the Andean region as the eighth centre of diversity in the world. (Castillo, 1995) Peru alone is considered among the twelve mega-diverse countries. As one non-Peruvian scientist described, "the Earth is a queen, her crown is in tropical countries, and the jewels of this crown are in Peru." (del Rio Mispireta, 1994)

Intellectual Property Framework

For many years the Andean countries, like many of its Latin American neighbours, remained outside the Paris Convention, preferring instead a series of regional accords on intellectual property rights.⁵³ Lately this has begun to change, although as of February 19, 1994, the only recent adherents from the area to the Paris Accord were Bolivia and Chile.

⁵² We had planned to include a separate section on Brazil, as we had heard that the proposed Industrial Property Bill was going to regulate the use of genetic resources. Our contact in Brazil informed us that while various groups have been trying to persuade the government to prepare legislation regulating access to genetic resources, there are no concrete initiatives underway to draft any such bill. The debate underway on the Industrial Property Bill has focused on how far patent rights should be extended. We were told that naturally-occurring matter will be unpatentable as such; as of May, 1995, the bill provided that "living beings, except for transgenic microorganisms" are unpatentable, however the definition of "transgenic microorganisms" has been controversial.

⁵³ A few Latin American countries were parties to the Paris Convention from its inception, including Brazil, Cuba, the Dominican Republic and Mexico. Haiti, Argentina and Uruguay joined about 20 years ago. Most of Latin America was party only to one or more regional accords, such as the Montevideo Convention of 1889, and the various Pan-American Conventions (1902, 1906 and 1910). (Ladas, 1975)

The Andean Pact was established by the Cartagena Agreement (officially, the Andean Sub-Regional Integration Agreement) in 1969 between Colombia, Peru, Bolivia and Ecuador, joined by Venezuela in 1974. The Agreement anticipated the establishment of common policies on agricultural development, economic policy and development, industrial programming, and tariffs. In particular, a common intellectual property law was established for all the member countries.⁵⁴

A recent series of amendments published in October, 1993 substantially changed the protection available, particularly with respect to plant varieties, pharmaceuticals and biotechnological inventions. The Andean Pact countries now will grant patents "in all fields of technology," although exclusions remain for "animal species and races" and the essentially biological processes for their obtention; substances "which already exist in nature or which replicate them"; and pharmaceutical products included in the World Health Organization list of essential medicines. (Correa, 1994; Bentata Hoet, 1994a)

Eugênio da Costa e Silva pointed out in a recent article that these provisions include sections that may be used by local and indigenous communities to protect traditional practices and knowledge. In particular, he points to the protection afforded industrial secrets, which can last as long as the criteria for obtaining the protection apply, in other words, potentially in perpetuity. (da Costa e Silva, 1995) (It may be noted that da Costa e Silva assumes, without discussing, that knowledge disseminated within, but limited to, particular local or indigenous communities would meet the requisite tests of secrecy.)

With respect to **plant breeders' rights**, as of January, 1994, none of the Andean Pact countries were members of either version of UPOV. However, Decision 345 provides for protection for new plant varieties invented "through the application of scientific knowledge to plant improvement." (Bentata Hoet, 1994b; Caillaux, 1994) This definition would appear to exclude varieties obtained from traditional breeding methods.⁵⁵

The Decision also excludes newly discovered varieties from protection. Jorge Caillaux and Brendan Tobin point out that for countries with extensive unknown plant species, this latter exclusion is contrary to their national interest: "it creates the anomalous situation that discoveries

⁵⁴ A copy of the Cartagena Agreement translated into English is available in: John P. Sinnott, *World Patent Law and Practice: Patent Statutes, Regulations and Treaties*, Volume 2J (Matthew Bender 1994), "Andean Pact."

⁵⁵ Jorge Caillaux suggests in an article that in theory, members of indigenous groups or farmers in the Andean region could "request legal protection to be granted for their work in "traditional" breeding, notwithstanding the fact that the UPOV system as a whole has been designed for completely different realities and societies. Argentina, Bolivia, Chile, Mexico and Peru have seed regulations with some of the UPOV elements, although in Peru it has not yet had practical application." (Caillaux, 1994) Presumably these "seed regulations" are other than those contained in Decision 345 (eg, perhaps they are part of the local laws of Peru and the other countries noted), since Caillaux notes later in the article that Decision 345 would not extend to traditional breeding. Eugênio da Costa e Silva also points out that a breeders' right may only be granted to natural persons or legal entities, which may necessitate indigenous communities obtaining "legal personality" if they are to register a new plant variety. (da Costa e Silva, 1995)

may obtain protection in countries party to UPOV, but not within the country of origin itself." (Caillaux/Tobin, 1993, Caillaux, 1994)

As under UPOV, a plant variety must be new, homogenous, distinguishable and stable. A plant variety will be considered new if either its reproduction material or a product of its harvest has not been sold or applied by its owner for commercial purposes. The holder of a plant breeders' right under the law will be able to prevent third parties from carrying out activities of production and commercialization of the plant variety's reproduction material, including importing and exporting it, without the holder's prior consent. (Bentata Hoet, 1993b)

The Decision also follows UPOV 1991 in providing restricted protection of "essentially derived varieties." (Caillaux/Tobin, 1993) Caillaux points out that it is therefore possible that varieties essentially derived from a traditionally developed variety, as defined in the Decision, would be subject to protection, while the traditional variety itself falls outside the scope of the law (eg, as a newly discovered variety). Caillaux suggests that if the original variety is not clearly distinguishable from the protected one, then one could have the anomalous result whereby the original one may be restricted from access in the market by the protected variety. (Caillaux, 1994)

At present, draft implementing legislation is under discussion in the member countries. It is anticipated that by the end of this year, most of the Andean Pact states will have adopted national legislation to give effect to this Decision.

Other International Conventions

With the exception of Ecuador (which has observer status only), as of December 1995 all the Andean Pact member countries were members of the World Trade Organization.

All of the Andean Pact member countries have ratified the Biodiversity Convention. In response to the United States' rejection of the Biodiversity Convention, Venezuela stopped signing new agreements with the U.S. scientific institutions that were engaged in collection and screening of Venezuelan genetic resources. (Rosendal, 1994) It is not known whether this policy continues to date.

4.1.2 Current Ideas, Approaches and Activities

(a) 1994 Proposal to Regulate Access to Genetic Resources (Report, 1994)

(i) Introduction

When Decision 345 (on plant breeders' rights, discussed above) was approved, the Andean Pact countries agreed that by December 31, 1994 they would approve a Common Regime on Access

to Biogenetic Resources that would reflect and implement the Biodiversity Convention.⁵⁶ To this end, the Board of the Cartagena Accord asked the Environmental Law Centre of IUCN - The World Conservation Union (IUCN-ELC), with the assistance of the Peruvian Environmental Law Society (SPDA), to conduct extensive studies of the issues, and ultimately prepare a draft proposal and report. Over the course of the project, a series of consultations was held with regional and international experts, including those from UNEP, the FAO, the Secretariat Pro-Tempore of the Amazon Cooperation Treaty, universities, NGOs, individuals from Europe, Africa, Asia, North America, and representatives of indigenous groups from the Amazon region.

In addition, a second proposal was prepared, by the Colombian and Venezuelan Governments. These proposals have now been combined by the Andean Pact Working Group into a Draft decision. The expert Working Group will hold its final meeting June 21 - 23, 1995; it is expected that in July, the draft will be sent for approval by the Ministers of member States within the Andean Pact Commission.

(ii) Elements of the Draft Decision

(1) *Basic Principles*

Like the Biodiversity Convention, the proposal begins from the premise that states have *sovereign rights* over their natural resources, and the authority to determine *access* to those resources. Under the decision, member states will declare all genetic resources to be part of the national patrimony.

The draft covers access to genetic resources, derivatives, synthesized products⁵⁷ and associated knowledge, innovations and practices of indigenous and local communities. All access for scientific, commercial or industrial purposes is to be regulated by the member states, on the basis of *prior informed consent* and *mutually agreed terms*. The draft is explicit that the source country government must be a party to any decision on access -- including in situations where the genetic resource is on privately owned property. A multidisciplinary body will be established to assist the designated national competent authority in ensuring that access contracts are in the national interest.

⁵⁶ The original stated goal included adopting a common regime to guarantee biosafety, i.e., the control of biotechnologically-modified organisms released into the environment. It was decided early in the process that since the biosafety issue was the subject of on-going intense debate within the context of the Biodiversity Convention, it would be preferable to set that issue aside for the time being.

⁵⁷ The inclusion of synthesized products is recognized to be a contentious proposal. The concern expressed is that this will discourage investment in research and development in Andean Pact countries.

Applications for access will be required to include information about the party seeking the access, the tangible and intangible resources involved, proposed uses, the providing parties, national scientific partners, and agreement of indigenous or local communities for access to and/or use of their innovations, knowledge or practices.

The draft proposes to include special conditions that will ensure that material in *international genebanks* of IPGRI remain accessible and not subject to excessively onerous access procedures.

The proposal also adopted the FAO description of *farmers' rights*, and the concept that those rights are vested in the international community as trustee for present and future generations of farmers, for the purpose of ensuring full benefits to farmers and supporting the continuation of their contributions, as well as the attainment of the overall purposes of the International Undertaking on Plant Genetic Resources.

It is not known whether either or both points from the proposal were included in the draft decision.

The final basic principles underlying the proposal were *cooperation* and *reciprocity*. (Part I, Art. 4) The report stressed the need to establish a relationship of mutual cooperation among member states, and create mechanisms to facilitate access to genetic resources among themselves. The second element of cooperation arises from the fact that the distribution of resources does not follow political borders; many resources are shared by two or more countries.

The reference to reciprocity is also important. The proposal would have required member states to "cooperate with other States and promote reciprocity through the adoption by those States of appropriate national legislation in conformity with the Convention on Biological Diversity." This would also underscore the importance that all interested nations, not only those within the Andean Pact, should ascribe to the Andean proposal; it could potentially set a standard that would then, by means of reciprocal arrangements, apply internationally.

Again, because the draft decision was only just prepared, it is not known whether these elements of the proposal are reflected in its provisions.

(2) *The Certificate of Origin*

Under the IUCN-ELC/SPDA proposal, access to genetic resources was to be made subject to *governmental authorization*, which would take one of two forms: (1) a valid Certificate of Origin, for *in situ* resources, and (2) a Material Transfer Agreement, for *ex situ* resources. Every subsequent transfer of the accessed material would have to be accompanied by the authorizing instrument, to provide continuing scrutiny of the research or other endeavour, and ensure that its terms are adhered to. This proposal apparently is likely to be included in the Decision. Indeed, the draft Peruvian implementing legislation on Decision 345 (plant breeders' rights) includes the certificate of origin scheme.

The purpose of this system is to provide a link between the access requirements and intellectual property regimes: patents and other intellectual property rights would only be granted upon presentation of the Certificate as proof of prior informed consent for the use of genetic resources, and, where relevant, knowledge, innovations and practices of local or indigenous communities.

The original proposal recommended inclusion of the following sanction for breach of these provisions: any registration, patent, breeder's certificate, trademark, or other type of intellectual property right obtained without first presenting a valid Certificate of Origin or Material Transfer Agreement, would be null and void. It is not known whether this sanction was retained in the draft decision.

The regime is designed to ensure that meaningful "prior informed consent" is obtained from all the interested parties, including the State and the actual provider (which may be an indigenous or local community). To this end, the draft requires that an access agreement be concluded between the provider and the recipient.

While it is not known yet how the draft decision addresses these issues, the IUCN-ELC/SPDA proposal specified a series of issues that must, at a minimum, be addressed in the conditions for access. The list included:

- obligations to ensure the activities do not cause genetic erosion or deterioration of the ecosystem;
- terms of transfer of the accessed material to third parties;
[This may be used to ensure that future uses of the resources by others are reported.]
- obligations related to intellectual property rights;
[The proposal noted that member States could stipulate that the genetic material is not subject to intellectual property rights.]
- obligations relating to participation in economic/financial benefits;
- obligations for in-kind benefit sharing, such as technology transfer, research, training and education programmes in the member State granting access;
- obligations to deposit duplicates of all collected materials in designated institutions;
- restrictions as to exclusivity obligations;
- confidentiality clauses;
- obligations regarding availability of research results;
- obligations to submit to an environmental/economic/social impact assessment;
- obligations regarding association with an approved national, regional or international institution, designated by the member States;
- obligations regarding choice of laws [eg, that choice of laws always be that of the resource-providing State].

(3) Local and Indigenous Communities

Indigenous organizations from Colombia, Bolivia, Peru and Ecuador, together with the Coordinator of Indigenous Organizations of the Amazon Basin, sent a strong message to the Andean Pact and negotiating experts during their last meeting, concerning the draft decision. These groups threatened to use all legal means at their disposal to impede the collection of resources in their territories, and to draw international attention to any unapproved use of their knowledge, innovations or practices, unless two demands were met:

1. recognition of indigenous and local communities' rights over their knowledge, innovations and practices; and
2. the establishment of a special regime to govern collection of resources in their territories.

The latest draft decision does recognize rights of indigenous and local communities over their knowledge, innovations and practices. It does not however establish a mechanism for identifying the rights over these intangible resources at the national level. Proposals are being advocated in Peru for the establishment of a register of indigenous interests over the product of their intellectual effort.

The issue whether, or rather, to what extent, to recognize indigenous and local community rights over knowledge, innovations and practices, was contentious during the development of the draft decision. Some states advocated recognizing the value of this knowledge, etc., the interest of these people, and provide for equitable sharing of benefits. However, concern was expressed that recognition of their rights over this material would imply the creation of a new form of intellectual property regime, which would prove impossible to achieve.

The Peruvian delegation persuaded a majority of states that recognition of the right was crucial, and indeed necessary to comply with Article 8(j) of the Biodiversity Convention, as well as other international obligations.

If included in the final decision, this could mark a radical evolution in the nature of intellectual property rights, as well as a significant development in the interpretation, application and implementation of the Biodiversity Convention. It would set a very important precedent as to the import of Article 8(j).

The provision as set out in the original IUCN-ELC/SPDA proposal stated that member states "recognize the rights of indigenous and local communities over their traditional knowledge, innovations and practices, and the consequent authority to decide whether and how to share such knowledge, innovations and practices." (Part I, Art. 3)

The commentary to this section noted that "[r]egulating access to genetic resources implies the need to consider the *intangible element linked to the resource itself*, ie. knowledge which is constantly evolving and is the fruit of many years and, in certain cases, centuries of maturing." (emphasis added)

It may be seen that this is the first extension of *intellectual* property rights (rather than physical property rights, which forms the basis of the access agreements) to biodiverse genetic resources whose value is not in their novelty, but in almost the inverse: their conservation.⁵⁸

While clearly such rights would significantly alter current aspects of intellectual property law, the underlying premise of this extension is not necessarily in opposition to the underlying premise of traditional intellectual property, especially patent, rights. That is, both derive from the benefit the protected product brings to the community, state or world. Just as patent rights made something that previously would have been freely available into something privately owned (and no doubt were viewed with suspicion as a result), and just as plant breeders' rights took this private protection one step further, extending intellectual property rights into previously uncharted territory, so now would this extend the rights yet further. In every case, the protection afforded must be justified on the basis of a public good, held to override the concerns of monopoly control, restricted access, and higher transaction costs the protection entails. In this case, the appeal may be to the need to conserve biodiversity, or sustainable agricultural practices.

It is unclear, however, what the proposed limits of these new rights would be. Would it be limited to wild germplasm, that has been conserved? Or would it extend to cultivated varieties, in a development parallel to that of farmers' rights? It is also unclear how claims of rights could be verified, or even allocated -- if a species is found in several regions or countries, who could claim the rights? Some constraints would have to be added, to contain the potential consequences. However, as has been demonstrated by the evolution of the concept of farmers' rights under the auspices of the FAO, such seemingly intractable problems can often be clarified and resolved, with work and discussion.

Special conditions are to be established for obligations concerning access to genetic resources of indigenous and local communities. The draft requires that those seeking access to indigenous knowledge, innovations and practices must conclude an agreement directly with the relevant indigenous peoples, as a condition precedent to granting rights of access to associated genetic resources. This provision is designed to enable the indigenous and local communities to secure compensation.

The draft does not include any special provisions regulating collection of genetic resources on indigenous lands.

⁵⁸ The commentary suggests that the intention is not simply to recognize an intellectual property component in indigenous knowledge concerning uses and applications of a particular resource, but in the resource itself.

It can readily be seen from this brief overview that the discussions that have taken place within the Andean Pact, and possibly the decision when it is finalized, could have far-reaching implications both for access regimes (the certificate of origin) and for indigenous and local community rights. As will be seen, very few states have enacted legislation to implement the provisions of the Biodiversity Convention; consequently, the precedent established by the Andean Pact countries (not least because it is a regional organization of five nations) may have consequences beyond its borders.⁵⁹

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⁵⁹ Indeed, the Andean Pact draft was singled out in a recent report by the Secretariat for the Conference of the Parties to the Biodiversity Convention, that looked at national and international experience in implementing the Biodiversity Convention. (See: "Access to Genetic Resources and Benefit Sharing: Legislation, Administrative and Policy Information," report by the Secretariat for the 2nd meeting of the Conference of the Parties to the Convention on Biological Diversity, UNEP/CBD/COP/2/13, October 6, 1995.)

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4.2 Costa Rica

4.2.1 Background

Resources

Costa Rica, positioned between North and South America, and bordered by both the Caribbean Sea and Pacific Ocean, possesses a wealth of different habitats, including evergreen rainforests, dry monsoonal forests, volcanic and orographic mountain ranges running north and south, monsoonal trade winds blowing east to west, and Nearctic and Neotropical biogeographic regions. As a result, there are an estimated 500,000 species of plants and animals within the small country. (Sandlund, 1991; Alikodra and Caldecott, 1992)

Most of the land is privately held, and has suffered a high deforestation rate, primarily because of the economic attractions of agriculture and ranching. To arrest this trend, the Costa Rican government instituted a strategy designed to conserve its remaining natural resources, and simultaneously build the country's financial, intellectual and technological capital base. There were several elements to the government's approach:

- (1) establishment of clearly defined, private and public "protected areas", encompassing 27% of the national territory, and organized into a National System of Conservation Areas (SINAC);
- (2) creation, by law, of a National Institute of Biodiversity (INBio Instituto Nacional de Biodiversidad) to conduct an inventory of the country's biological resources and, working with national and international institutions, encourage appropriate economic and intellectual use of those resources;
- (3) establishment of a strong legal framework regulating access to and control of biological samples in Costa Rica; and
- (4) Implementation of social policies for the creation of a skilled and educated workforce, including a base of scientists, technicians, and well developed laboratories at local universities. (Sittenfeld & Artuso, 1995)

Particular aspects of this strategy are outlined in greater detail, below.

Intellectual Property Framework

Costa Rica is not a party to the Paris Convention, nor to UPOV (either version). Costa Rican law prohibits the grant of patents over genetic material of wild flora, fauna and seeds. Costa Rica's patent law excludes from the definition of "invention" for purposes of patentability: plant varieties and animal breeds, procedures that are essentially biological for obtaining vegetable or animal

specimens, as well as microbiological procedures and the products obtained thereby. (Law No. 6867, the Law Governing Patents for Inventions, Industrial Drawings, and Improvement Models, Article 1(3)(b).)

The law does allow for patents on pharmaceuticals, as follows: "medicines, articles and substances for therapeutic use and processes and methods for the production or synthesis of substances having a therapeutic effect may only be patented, *to the extent that such products, processes and methods are manufactured or carried out entirely in the country.*" Patents not registered in the applicant's home country are not registrable, nor are patents for pharmaceutical products not in use or operation in the home country. (Article 2(7), emphasis added.)

The Wildlife Conservation Law⁶⁰ has been held to declare that: "The production, management, extraction, commercialization, industrialization, and use of genetic material of wild flora, fauna and seeds, are declared to be of public interest, and ... part of the National Patrimony. Patents over them cannot be granted." (Medaglia, 1994)

Other International Conventions

Costa Rica is a member of the World Trade Organization, and has ratified the Biodiversity Convention.

4.2.2 Current Ideas, Approaches and Activities

(a) National System of Conservation Areas (SINAC)

In July, 1990 legislation was passed to create seven biodiversity management units, called Conservation Areas, consolidating various parts of the protected areas that existed at the time throughout the country -- national parks, forest reserves, biological reserves, experimental stations, recreation areas, protected zones, national monuments and wildlife refuges. All were redefined with a new common objective: to preserve biodiversity, and conserve the ecosystems associated with it. Over time, the Government increased the land area through purchases and compensated expropriation of private property, especially that adjacent to established Areas that could link dispersed parts of an Area. Together, the Areas now cover 27% of the land area of Costa Rica.

Each Conservation Area has been given a considerable degree of autonomy, with its own budget and management structure. The headquarters of the National Parks Service acts primarily as a facilitator and coordinator, with management responsibility and decision-making given to the

⁶⁰ This law is discussed at greater length below.

representatives of MIRENEM (the Ministry of Natural Resources, Energy and Mines) located in the Conservation Areas themselves.

All the people within the administration of each Area live within the area itself -- a significant change from the previous arrangement, where each park had its own director, all of whom lived in San José, and the park rangers were prohibited from living with their families within the park area. The reorganization was designed to maximize the benefits that would accrue directly to the local communities from the Conservation Areas, from both job creation (most management staff are of local origin) and financial revenue.

Each Conservation Area has an Endowment Fund, intended to provide permanent funding from investments, to cover operating costs in accordance with each Area's priorities. For example, the Guanacaste Conservation Area's Fund included income from several separate "debt-for-nature" swaps (ie, from international donors and the Costa Rican Government); direct donations; and sale of services.

(The above is based on information contained in: Alikodra & Caldecott, 1992; Sittenfeld and Artuso, 1995; and Sandlund, 1991)

(b) National Biodiversity Institute (INBio)

INBio was created in 1989 as a private, non-profit institution, with a mandate to conserve Costa Rican biodiversity through facilitating and stimulating its use in both a non-destructive and sustainable way. Its board includes economists, lawyers, educators, journalists, chemists, botanists and ecologists, drawn from, among other places, universities, media, government ministries and banks.

Broadly speaking, INBio is engaged in two endeavours:

(i) It is conducting a ten year national inventory of Costa Rica's estimated 500,000 wild species located within the National System of Conservation Areas. The objectives are to learn where they are located, to collect information on their biology, chemistry, ecology, behaviour, and genetic make-up, and to ensure they are correctly identified, both to manage the data and also to relate them to scientific information around the world. This inventory is conducted by parataxonomists, trained from local communities and working out of field offices located in the Conservation Areas. The specimens are added to the National Biodiversity Collections, and the information is entered onto computer databases for accessing by a range of users that include farmers, school children, academic researchers, and industrial scientists. To this end, INBio and Intergraph Corporation of Alabama, U.S.A., have agreed to develop together a computerized Biodiversity Information Management System (BIMS) for INBio's use. It was agreed that should the project produce commercially marketable software, INBio and Intergraph will share the income from the software sales. The structure of INBio's databases, and the data from the inventory, will be in the public domain.

It is interesting to note that INBio's original agreement with MIRENEM -- which established INBio and set its mandate -- was revised in October, 1994 to prohibit the commercialization in whole or in part of the samples collected for the inventory. The agreement states that breach of this provision will lead to the rescission of the agreement, and application of the penal provisions of Costa Rica's Wildlife Conservation Law.

(ii) INBio conducts and facilitates research to identify properties of plants, insects and microbes with potentially useful properties for agriculture and medicine.⁶¹ This is achieved primarily through collaborative research agreements. INBio's partners have included Merck & Co., Cornell University, the Natural History Museum (London), the University of Minnesota, the University of Pennsylvania, the US National Cancer Institute, the Smithsonian Institute, the Strathclyde Institute for Drug Research (Scotland), as well as the Costa Rican Ministry of Natural Resources, Energy and Mines, the National University of Costa Rica, and the Organization for Tropical Studies (Costa Rica). The substantive terms of the collaborative research agreements are discussed below.

Several of the leading figures in INBio recently summarized the characteristics that contribute to INBio's success:

- by-laws that emphasize the conservation of wildland biodiversity through non-damaging use;
- a commitment to generating income from wildland biodiversity, to meet wildland biodiversity management costs and to boost the country's GNP; a strong national orientation;
- a policy of hiring nationals for positions at all levels;
- cultural awareness and involvement in national policy;
- multiple goals and multiple products;
- a budget determined by goals and products;
- a commitment to rigorous science;
- dependence on taxonomy and natural history as primary technological tools;
- responsiveness to challenges and recommendations related to biodiversity management and use;
- a commitment to serving as a source of information on biodiversity management and use; and

⁶¹ Sandlund provides a useful hypothetical example of how INBio's ecological screening process and computerized National Dissemination and Extension Service (which makes the information widely available) can combine advantageously. "In a medical or industrial process an enzyme is needed to degrade a particular type of substance X. The same type of substance has been found in the leaves of a plant species A collected by INBio. These leaves are poisonous to most animals, but INBio's data entry on the plant species A says that an insect larvae of species B feeds on these leaves. Thus INBio collects insect larvae B and their guts are analyzed for enzymes that may be able to degrade substance X. Once the correct type of enzyme is isolated from biological material, it may easily be produced in biological cultures or synthesized. However, the first step in identification has been made much simpler through taxonomic and ecological information." (Sandlund, 1991, p. 16)

- a policy of sharing data and information with other parallel users but charging commercial users. (Gámez, et al., 1993)

INBio's legal counsel, Carlos Manuel Rodríguez Echandi, added the importance of close collaboration between INBio, the government and the multiple owners, custodians and caretakers of the wildland resources. (Echandi)

INBio has been actively involved in working with other countries to develop projects and institutions based on the INBio model. To this end, it has developed collaboration agreements with Kenya, Indonesia and Mexico, and participated in numerous workshops and studies. This is particularly noteworthy in view of concerns that have been expressed by some to the effect that general institution of INBio-like organizations throughout the tropics could lead to a "bidding war" for bioprospecting contracts with third parties like Merck or other potential partners. (Juma, 1993)

(c) Legal Framework

The third element that was required for an effective regulatory regime of Costa Rica's biodiversity resources, was a clear legal framework. It was found that the lack of clear legislation on land ownership made collecting specimens from those areas fundamentally risky; uncertainties arose as to who had the requisite authority to grant legitimate access, and set the terms and conditions for that access. (Sittenfeld and Artuso, 1995)

To address this, a new Wildlife Conservation Law was passed in December, 1992. Under its terms, as judicially interpreted⁶², fauna and wild plants are declared to be in the public domain, and to constitute a renewable natural resource that is part of the National Patrimony of Costa Rica.

INBio's policy has been that all basic information in its inventory -- what species are where, and their natural history -- as well as new biodiversity inventory information, has been acquired from the public domain, and therefore must remain in the public domain. (Janzen, et al., 1993) This policy was reached partly in the hope of opening this information up to developing countries, after those involved in designing the policy had experienced difficulties in accessing biodiversity information held in various forms and places in developed countries. (Janzen, et al., 1993)

Under Article 4 of the Wildlife Conservation Law, again as interpreted by the Constitutional Court: "The production, management, extraction, commercialization, industrialization, and use of genetic material of wild flora, fauna and seeds, are declared to be of public interest, and...part of the National Patrimony. Patents over them cannot be granted. The State holds the exclusive right to commercialization of genetic resources...and the General Administration of Wildlife of MIRENEM will hold the power to grant concessions to do so. The foregoing -- except for concessions extended

⁶² The wording of the law was unclear, and resulted in conflicting opinions within a Commission studying it. The legislation was then submitted for review by the Constitutional Court, which established the accepted meaning of the disputed provisions. (Medaglia, 1994)

by the said Administration -- will stipulate the terms of this law and their regulation." (Medaglia, 1994)

As noted above (in the description of Costa Rica's intellectual property framework), the prohibition against patenting genetic material of wild flora, fauna and seeds is consistent with the provisions of Costa Rica's patent law, which specifically excludes from the definition of "invention" for purposes of patentability: plant varieties and animal breeds, procedures that are essentially biological for obtaining vegetable or animal specimens, as well as microbiological procedures and the products obtained thereby. (Law No. 6867, the Law Governing Patents for Inventions, Industrial Drawings, and Improvement Models, Article 1(3)(b).)

The Wildlife Conservation Law is thus explicit that MIRENEM has the right to grant permits for the access and use of genetic resources. Under MIRENEM's agreement with INBio, MIRENEM agrees to grant INBio permission to collect samples for use in scientific research and bioprospecting, under certain terms and conditions. In particular, the agreement stipulates that the samples cannot be commercialized in whole or in part. INBio agrees to put 10% of its total budget for each research project towards the management and conservation of the Conservation Areas, and to transfer to MIRENEM 50% of any economic or material benefits that it receives under the contract, which will be put exclusively to management and conservation of the wild areas managed by MIRENEM. The agreement also contains a number of provisions requiring continued information flow to MIRENEM on each project, in particular to ensure that the bioprospecting is conducted in an ecologically appropriate manner. Training and technical development are also prominent aspects of the terms of agreement: INBio undertakes to provide training workshops and courses for MIRENEM personnel.

The Wildlife Conservation Law accordingly forms the foundation for INBio's work, and the authority and parameters for its bioprospecting contracts with third parties.

Finally, it may be noted that the Wildlife Constitutional Law has been determined to be consistent with the Costa Rican Constitution, in particular the provisions that give the Legislative Assembly exclusive jurisdiction over the "Nation's own property" (Article 121.14 of the Constitution), and the provision that states that "the protection of [Costa Rica's] natural beauty" must remain under the protection of the State. (Article 89). (Medaglia, 1994)

Medaglia points out that this establishes biodiversity as a property right in Costa Rica. He analogizes the right to the property right to minerals beneath the surface -- the surface rights may be privately held, but the mineral rights remain in public hands. He notes that, "This type of property [biodiversity], even when it is private hands, is not subject to deposition [presumably, disposition] by individuals." (Medaglia, 1994, p. 6)

This lays an interesting foundation both for state control of ecological matters (to conserve biodiversity), over private property; it establishes a clear line of authority and responsibility for issues of access to and use of genetic resources; and ensures that the state controls property rights claimed in and arising out of such resources, including notably intellectual property rights. Such

a bifurcation of rights would appear to have implications for claims of indigenous and local populations to a property right in resources maintained, developed and conserved over many years: such rights would be dependent presumably on grants or agreements with the state.

(d) Terms of Access to Resources: INBio's Contracts

INBio set a groundbreaking precedent with its agreement granting access to Merck & Co. to Costa Rican genetic resources. While the precise terms of that agreement have never been made public, their general content has, along with the type of terms that INBio includes in all its bioprospecting agreements.

The Merck deal, signed in 1991, provided Merck with exclusive access, for a period of two years, to 200 species selected by Merck from a catalogue provided by INBio. This catalogue was compiled using species that Merck already knew how to obtain in quantity, either because they were produced in captivity or from known wild stocks. Samples of the chosen species were to be collected using agreed techniques and provided to Merck, with repeat supplies in reasonable quantities available upon request. In exchange, Merck paid US\$1,000,000 up-front, and agreed to pay INBio a one to two per cent royalty on derived products. Consistent with its agreement with MIRENEM, INBio would pay at least half of any royalties received to SINAC to cover the costs of managing and conserving the Conservation Areas. (Alikodra and Caldecott, 1992)

Certain elements are also known of INBio's agreements with Cornell University, and that with the Scottish Strathclyde Institute for Drug Research. In particular, they provide for INBio to share in royalties paid to any of INBio's collaborators on patented products resulting from that collaboration. (Alikodra and Caldecott, 1992)

Alikodra and Caldecott noted in their study that the patent system "is a key element in these agreements because, in order for a patent to be granted, the inventor must demonstrate an unbroken sequence of research, development and modification of a novel material which will lead back to Costa Rica, and therefore to INBio." (p. 9)

Other contractual provisions sought by INBio in bioprospecting contracts include provision for training Costa Ricans within the research and development facilities of the venture partners, and commitments to transfer part of the product development process to Costa Rica. As Alikodra and Caldecott point out, "As the latter is implemented, INBio would seek to provide at higher cost extracted, partially fractionated and bioassayed materials, rather than raw samples. This strategy has been adopted because, while royalty revenues on commercial products are potentially significant in the long term, it would be even more desirable for the Costa Rican economy to capture, directly or indirectly, part of the R&D investment in each product developed." (p. 10)

INBio contracts with commercial partners now include the following terms and conditions: (Echandi):

- direct payments in cash and barter
Direct compensation up-front is required to enable INBio to develop and conduct the sampling, screening and partial characterization process, as well as to train and finance local scientists. In addition, it serves to finance conservation programs right away.
- payments from INBio to SINAC
The contracts provide for payment of a significant percentage (up to 10%) of INBio's initial project budget, and up to 50% of royalties, for the cost of maintaining the Conservation Areas.
- royalty payments from the commercialization of the biodiversity materials
The contracts provide for "a significant fair royalty" paid on net sales to industry from the commercialization of the genetic resources. INBio's legal counsel notes that the companies' willingness to pay this relates to the fact that INBio is not simply providing raw materials, but has systematically maintained the resources and characterized them, at considerable cost.
- technology transfer
In particular, assistance is required in moving drug research and development to Costa Rica, to develop an infrastructure to enable Costa Rica to compete seriously, using her own wealth of resources.
- minimal exclusivity
INBio's legal counsel points out that this is a difficult clause to negotiate: the commercial partner wants to be the sole recipient of the samples, and deny its competitors the opportunity to conduct research on the same specimens. Costa Rica recognizes that this may pose problems, but that some guarantee of exclusivity is required if the contract is to be executed.
- ownership of the physical samples and patent rights
The ownership of the samples and extracts must be clearly defined in the agreement, and provisions made for the extract to either be destroyed after use, or remain subject to the INBio royalty. To quote INBio's legal counsel: "Patents represent such an administrative headache and entail such high legal costs that INBio would much rather have a solid commercial contract guaranteeing a royalty than own the patent outright." In addition, as he points out, Costa Rican patent law does not allow patents on a product produced by a living organism.

- use of chemical synthesis

One of the differences between users of genetic resources for research purposes, and those for commercial ones, is the contrast in the quantities required. While researchers usually require sufficiently small amounts to avoid altering the ecology of the protected area, commercial applications of novel chemicals or substances require vast quantities, which could not be satisfied without damaging the wildlands.

INBio encourages its commercial partners to consider Costa Rica their first choice for agricultural production of raw materials, or alternatively, to establish chemical synthesizing industries in Costa Rica, as alternative, ecologically acceptable ways of satisfying the demand.

In INBio's experience, the needs and objectives of both sides in a bioprospecting venture can be met through agreements that provide the source country with advance payments, royalty rights, rights to supply future raw materials, research exchanges and funding, access to markets and technology, and direct payments for conservation. Benefits can be directed both to conservation and to local peoples, and contribute to research efforts, without requiring either new definitions of property rights or special legislation. (Echandi)

Finally, it is interesting to note that from INBio's perspective, intellectual property laws do not impede biodiversity conservation, but rather can be used to benefit it, through arrangements that capture some of the economic benefit and channel it back to conservation of the resources. Again, to quote Echandi: "The greater the range of intellectual property protection available in a country, the more choices the inventor [has] to protect the fruits of research, development and marketing. Developing nations seeking to promote biodiversity prospecting, domestic innovation, and technology acquisition should have a modern intellectual property legislation that includes regulation[s] on trade secrets, patent protection in a supportive economic and political climate. This new legislation should be tailored to balance rights between the private domain and the public domain." (Echandi)

As is discussed in greater detail in the companion literature review, the Merck deal, and INBio's contracting arrangements are not without its critics (see, eg, Menon, 1995); nevertheless, their success particularly in drawing funds, research and development into the country have established Costa Rica as a leader among developing nations. The INBio contracts have laid the framework for virtually all access agreements negotiated since then.

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4.3 Mexico

4.3.1 Background

Resources and Context

Mexico is another "mega-diverse" country, with a wealth of different plant and animal species. At the same time, its proximity to the United States' market, and especially its membership in NAFTA, place it in a unique position among developing nations, with unique pressures as well as opportunities.

Intellectual Property Framework

Mexico is a longstanding member of the Paris Convention. In 1991, anticipating the need to implement the intellectual property provisions of NAFTA, Mexico passed a new *Law for the Promotion and Protection of Industrial Property*, which took effect June 28, 1991. The law provides patent protection for biotechnological processes for pharmaceuticals and medicines, beverages and food for both animal and human consumption, fertilizers and pesticides, among others.

The law specifically excludes patentability of essentially biological processes for producing, reproducing or propagating plants and animals; biological and genetic material as found in nature; and plant varieties and animal races.

With respect to plant varieties, Mexico undertook in NAFTA to adopt plant breeders' rights legislation, and to accede to UPOV. To this end, it introduced the *Ley Federal del Derecho del Creador de Variedades Vegetales*. It is expected to adhere to UPOV 1978 this year (1995).

The Plant Breeders' Law would protect varieties of all plant species. It would provide a breeders' exemption, but marketing essentially derived varieties would require permission. As drafted, if a new variety presents "identifiable characteristics" of a protected one, then the original breeder's consent is required before filing for a plant breeder right. The farmers' privilege⁶³ is explicitly included in the legislation.

⁶³ The farmers' privilege with respect to plant breeders' rights is the privilege to re-use on their farms seeds from a protected variety. This concept, and other concepts of intellectual property law, are discussed in the companion literature review. The farmer's privilege is to be distinguished from the concept of farmers' rights under the FAO, discussed above.

Other International Conventions

Mexico is a member of the World Trade Organization, and has ratified the Biodiversity Convention.

4.3.2 Current Ideas, Approaches and Activities**(a) CONABIO: Establishment**

While considerable attention has been paid to Mexico's legislation on intellectual property, the legal framework for biodiversity issues is still in the early, developmental stage. Until 1992, these issues were addressed only in a fragmented way, by individuals in different government agencies, NGOs, and researchers working in academic circles.

On March 16, 1992, President Salinas de Gortari created CONABIO, the National Commission for the Knowledge and Use of Biodiversity. When it was formed, its supporting operative group included Salinas himself, the Minister of Social Development, and the heads of the Ministries of Foreign Affairs, Treasury, Energy, Commerce, Agriculture, Education, Health and Fisheries. Its fundamental task is to promote and coordinate national efforts to promote public awareness of the importance of biodiversity, to amass information about Mexican genetic resources, and to promote sustainable use of those resources.

(b) CONABIO: Activities

CONABIO's role is primarily one of promotion and coordination; in contrast to INBio, it does not itself engage in the collection of specimens. It is however in charge of developing a policy framework to govern access to Mexico's genetic resources. To date, it has commissioned a study of the various legal instruments currently in force in Mexico, that could impact upon issues of access to and use of genetic resources.

As of July, 1995, CONABIO had draft bilateral agreements on scientific and technical cooperation in biological data and information, to be signed with each of Australia, Cuba, Costa Rica and the United States.⁶⁴ Copies of draft memoranda of understanding with the U.S. National Biological Service of the Department of the Interior ("NBS"), and the Australian Nature Conservation Agency ("ANCA"), were provided to these authors.

⁶⁴ We were advised by Mexican government officials that the draft agreements were "about to be signed" as of July 13, 1995.

The NBS agreement establishes a framework for future cooperative activities "in developing, accessing, analyzing, managing and communicating biological data and information." Among other things, it anticipates cooperation in the "development of biological data information relating to the responsibilities of the parties under international conventions and agreements"; "exchanges of biological data information relating to terrestrial, aquatic and coastal/marine environments"; "policies and guidelines for public access to biological data information"; "quality assurance and quality control for biological data information"; and "encouraging the use of biosphere reserves and protected ecological research areas, and networks of such areas, for developing biological data information and demonstrating applications of biological data information." [Article II, 1 (l), (a), (b), (d) and (j)] It also anticipates cooperative efforts in documenting, assessing and monitoring biological data information, as well as in communicating the information among the users.

The memorandum of understanding establishes a framework for such cooperative ventures, but the document provided does not set out the details -- for example, the terms of access to the physical biological resources, or the intangible information obtained therefrom, or rights of ownership or control over the intangible information. It does anticipate in general terms that the parties would provide "access to research technologies and infrastructure relevant to the programs of the Parties." It will be interesting to see how subsequent agreements elaborate on this framework, as the cooperative activities develop.

The Australian agreements anticipate "the exchange of expertise and ideas in the conservation of biodiversity" between the two agencies, noting the similarity of the ecological challenges faced by the two countries -- large expenses of arid land, tropical rainforests and temperate forests. The context of the agreement is explicitly that of the Biodiversity Convention: one of the stated principles of the agreement is "to develop and enhance the links between the two organizations [ANCA and CONABIO] to further both Mexican and Australian Government obligations under the Convention on Biological Diversity and Agenda 21."

The Agencies agree to cooperate in projects through both information and personnel exchanges, on issues that include "policies and principles for access to genetic resources."

Further cooperation is envisaged on matters relating to wildlife management (with explicit emphasis placed on sustainable use of wildlife); biological databases; the assessment, establishment and management of nature conservation reserve systems; and ecology, among others.

It is evident that the solutions being devised by individual states to questions of access to their genetic resources, are being crafted with wide, multilateral consultation, which significantly increases the likelihood of similar policies evolving in states around the globe.

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4.4 Africa

4.4.1 Background

Resources

A world classification system of bio-geographical realms prepared in 1975 classified Africa south of the Sahara within the Afrotropical Realm, which consisted of 29 bio-geographic provinces, each being an endemic floristic area comprising three kinds of rain forests, seven different woodland and savannah types, six aridlands, five mountain highlands, three island systems, four lake areas, and one Cape flora area. (IUCN 1975 paper, discussed in Cole, 1994, p. 56). However, these potentially valuable repositories of biological resources have not, to date, received their due scientific attention. (Cole, 1994)

Studies have noted that most African countries have continued to use a sectoral approach to biodiversity conservation, addressing specific problems in separate legislation, without sufficient cross-sectoral coordination among the approaches, or sufficient attention to the desired end results. Much of the existing legislation is outdated, inadequate, unenforced and ineffective. These problems are exacerbated by the proliferation of agencies and institutions, and the over-politicization of institutions and programmes. (Ajai, 1994.) Research and proper training in both the private and public sectors is considered critical, but has been hampered by lack of funding.

Since the establishment of the African Ministerial Conference on the Environment (AMCEN) in 1985, the majority of African member states have instituted measures and mechanisms for the traditional conservation of biological and other natural resources based on the *World Conservation Strategy* (IUCN/UNEP/WWF, 1980). AMCEN has encouraged all African countries to review their legislation for environmental considerations. However this has also been impaired by financial constraints. (Cole, 1994)

Intellectual Property Framework

In general, African states have viewed the existing international regime of intellectual property laws and rights as both constituting a financial barrier to their technological and other (health, agricultural) development, and inequitable, by failing to reward both the contributions of farmers and local communities in developing and conserving the landraces on which plant breeders -- whose innovations on those landraces is protected -- depend, and the contributions of indigenous and local knowledge to the protected "inventions". (Khalil, 1992.) Consequently, while most (if not all) African states are parties to the Paris Convention, none (with the exception of South Africa) have adhered to either UPOV Convention, at least as of January 1995. With the advent of the TRIPs Agreement, and the linking of trade sanctions to the failure to provide a set level of intellectual property protection, international pressure is being exerted to establish and enforce the TRIPs-level of IPR protection.

One interesting precedent may be found in the intellectual property law of Kenya, which was amended in 1989 to provide for a petty patent for traditional medicinal knowledge. (Gollin, 1993) Unfortunately, it is not known whether any such patents have been claimed, or to what effect.

A number of African countries are parties to a regional accord on intellectual property rights, known as the African Intellectual Property Organization (OAPI). The OAPI Agreement (Bangui, March 2, 1977) contains a number of interesting provisions relating to both genetic resources and indigenous knowledge.⁶⁵

Annex VII of the Agreement, "Copyright and the Cultural Heritage," Article 8, provides that "folklore belongs, in the first instance, to the cultural heritage." "Folklore" is defined for these purposes to mean "literary, artistic or scientific works as a whole created by the national ethnic communities of the member States, which are passed from generation to generation and which constitute one of the basic elements of the African cultural heritage." [emphasis supplied.] Article 46 specifies that "folklore" includes "scientific knowledge and works: practices and products of medicine and the pharmacopoeia, and theoretical and practical attainments in the fields of the natural sciences," as well as "technological knowledge and works: agricultural techniques, and hunting and fishing techniques." Article 8(5) specifies that the proceeds from royalties deriving from exploitation of these works "shall be used for cultural and social purposes. The conditions under which such royalties are shared shall be fixed in a rule to be promulgated by the competent national authority."

Article 45 specifies that, in addition to folklore, "collections and rare zoological, botanical, mineralogical and anatomical specimens" and "ethnographic material, such as...products of pharmacopoeia, traditional medicine and psychotherapy" shall be considered "as belonging to the cultural heritage of the nation".

The Agreement obligates member states to assure the protection, safeguarding and promotion of this cultural heritage, including the listing, assessment, classification, security and illustration of its constituent elements.

Of perhaps greatest interest are Articles 50 and 51 which state:

Article 50

- (1) It shall be forbidden to unlawfully denature, destroy, export, sell, alienate or transfer, in whole or in part, any of the constituent elements of the cultural heritage.
- (2) the absence of a special authorization issued by the designated competent authority, it shall remain forbidden to make a reproduction for gain, by any process whatsoever, including photographic reproduction, of any unclassified cultural

⁶⁵ This treaty, translated into English, may be found in John P. Sinnott, *World Patent Law and Practice: Patent Statutes, Regulations and Treaties*, Volume 2J (Matthew Bender 1994), "Malagasy", p. 299 *et seq.*

property, listed or not, ancient or modern, and considered as a constituent of the national cultural heritage within the meaning of the present Annex.

Article 51

In order to prevent its looting, loss or deterioration, the State shall assure the control of exportation, distribution, alienation and sale of unclassified cultural property, listed or not, ancient or modern.

Article 74 provides that any person who knowingly violates the provisions of Article 50 is liable to imprisonment of from one month to two years, plus a fine, without prejudice to damages.

These provisions could arguably apply directly to genetic resources, as well as to the use of indigenous and local knowledge. The definition in Article 8 of "folklore" -- which is made part of the cultural heritage -- is worded so as to apparently encompass local and indigenous knowledge, innovations and practices, and arguably even the conserved genetic resources themselves: they are "scientific works" passed from generation to generation.

Article 46 is even more explicit, by specifying that folklore includes scientific knowledge"; and Article 45 again extends protection to the specimens themselves.

Thus, the foundation is laid for the assertion of control over attempts to "denature, destroy, export, sell, alienate or transfer, *in whole or in part*" -- and presumably the genetic resources constitute "a part" -- of this cultural heritage. Article 50(2) is of particular interest when considered in the context of cloning and other genetic reproductions which are then used for commercial purposes: arguably any such reproduction of genetic resources that came from within the OAPI would contravene this article, unless authorized.

Other International Conventions

Most African states are members of, or observers to, the World Trade Organization (with certain exceptions, e.g. Ethiopia), and have signed and/or ratified the Biodiversity Convention.

4.4.2 Current Ideas, Approaches and Activities

(a) Tanzanian Experience

Community-level organizations have been extremely active in Tanzania in the conservation and utilization of biodiversity. Two types of such organizations exist: (1) government-negotiated local level community organizations, and (2) grassroots-initiated community level organizations.

Concern is expressed that the current institutional bias of the government-negotiated organizations, whose objectives are government formulated, could affect their performance; in addition, the financing is by donors, and on a project basis, which, it has been argued, "places great emphasis on economic reward, and this raises the question of what will happen when donors terminate funding for a particular project." (Kamara, 1994)

Three strategies are proposed by Kamara: (1) government and donor efforts should be localised as much as possible, to ensure the conservation and sustainable use of resources contained in the programmes is incorporated into the system of local or indigenous resource management and utilisation practices; (2) non-economic incentives are required, which are less prone to macro-economic turbulence and dependence on donors; and (3) local and international NGOs should cooperate with the local organizations over conservation practices which are in line with the principles laid down in the Biodiversity Convention.

(b) Cameroon Experience

Cameroon recently (1994) established a legislative framework for integrated management, conservation and sustainable use of forests, fauna and fisheries. (Law 94/01 of 20.1.94) The law provides that genetic resources in Cameroon belong to the state. No one is allowed to exploit them for scientific, commercial or cultural purposes, without authorization. The law goes on to stipulate that any financial or economic benefits that result from the use of Cameroonian genetic resources are subject to a royalty, to be paid to the state, at a rate and upon terms set by the Government. (Biodiversity Convention Secretariat Report, 1995)

Also in 1994, in response to a request from the Government of Cameroon, the U.S. Agency for International Development (USAID) sent Dr. Daniel Putterman to Cameroon for two weeks to meet with relevant actors in the Cameroon Government and NGOs, to listen to their concerns in the area of bioprospecting, and identify potential collaborators for future USAID-sponsored assistance in the area. In his report, Dr. Putterman detailed the existing regulatory context governing bioprospecting in Cameroon, and opportunities for improvement, which is summarized below. (Putterman, 1994.)

Cameroon's forests are among the most biologically-rich in Africa, containing an estimated 9,000 known species of plants, and forming part of a contiguous equatorial rainforest second in size only to the Amazon basin. However, the existing regulatory regime has "been inadequate to preserve Cameroon's rights to its genetic property in the case of bioprospecting, and has not allowed the country to capture a fair proportion of the value of these resources for conservation and economic development."

Regulation of bioprospecting in Cameroon is currently "a multidisciplinary endeavour", falling within the jurisdiction of more than one ministry. All foreign collectors must obtain a research permit from the Ministry of Scientific and Technical Research (MINRST), before they may remove samples of resources. These permits usually authorize removal of small quantities, usually

flora, without charge. The permits are negotiated on an individual basis, with no set formula for amount and type of material to be exported for research purposes. The Ministry of Environment and Forestry (MINEF), created in 1992 by a World Bank-sponsored government reorganization, is authorized to issue commercial exploitation permits for large-scale extraction of genetic resources for commercial purposes. MINEF negotiates an export duty with the buyer, using market prices as a guide to set the duty.

Neither procedure is considered to be an effective means to either preserve Cameroon's rights to its genetic resources, nor to ensure that it obtains a fair percentage of the resources' value. No mechanism is in place to enforce mandatory value-added processing in-count, nor to negotiate supply contracts, royalties, or ensure sustainable harvesting practices in the extraction process.

While it does not explicitly address any bioprospecting issues, the new Forestry Code was noted for its potential impact on bioprospecting. It redefines the system of rural land tenure, giving local communities the right to establish community forest reserves with sovereignty over the use of those resources. This is an existing tool that could, potentially, be a basis for local communities to become directly involved in setting terms for access to and use of genetic resources.

The report also notes that Cameroon intellectual property laws protect patents (including pharmaceutical patents), trademarks, copyright and "cultural patrimony."⁶⁶ Dr. Putterman noted that this "suggests the intriguing possibility that such cultural knowledge as indigenous medical cures may one day be covered under some type of intellectual property regime in Cameroon. Such protection would of course be territorial and limited only to Cameroon, although new inventions incorporating minor variations on traditional knowledge would, paradoxically, be eligible for patent protection in the industrialized nations." There is no trade secret law in Cameroon.

While Dr. Putterman concluded that "Clearly Cameroonian intellectual property law, like the system of research and commercial exploitation permits, leaves large gaps in the protection of national genetic and "intellectual" property," he noted that the government may prefer to first improve its regulation of the genetic resources, and accompanying folk knowledge where relevant, before turning to the intellectual property laws. In particular, it was suggested that immediate and simple steps might include the introduction of Material Transfer Agreements stipulating the rights retained by Cameroon to any sample removed from the country for research purposes.

The study noted the formation of a number of new local NGOs that may play significant roles in land use decisions at the village level, including with respect to bioprospecting at the community level, given the new community land tenure system. National NGOs are also forming, including several dedicated to natural resource management and conservation. A stated goal of one is the encouragement of equitable commercialization of genetic resources, including those discovered through traditional or folk uses, for the purpose of local community development. This same organization (Bioresources Development and Conservation Programme, or BDCP) was noted

⁶⁶ This is discussed above, under Section 3.4.1.

as a regional organization well positioned to lobby for reform of African national policies regulating bioprospecting. One noted consequence of this may be "the future harmonization of biodiversity property rights legislation in West and Central Africa."

Cameroon is a major source of a number of medicinal plants, most of which are harvested from wild populations. However, it has made no attempt to develop its own capacity to prepare medicinal plant extracts for sale on the world market, nor to link this trade to conservation and local community development. The report also notes that the country has obtained only a small proportion of benefits from the medicinal plant trade.

An example cited relates to *prunus africana*, a tree whose bark has important anti-cancer properties. However, the tree increasingly is being debarked illegally, which causes the tree to die, threatening extinction of the species. (African Round Table, 1994; Dr. Putterman refers only to "perceptions of over harvesting".) Meanwhile, a French company is the sole holder of a commercial exploitation permit to collect and export the bark to the European market. The European market was estimated at \$150 million in 1992; none of the profits are repatriated to Cameroon, whose citizens are paid only for the collection of the bark (at a rate, prior to currency devaluation, equivalent to 60-70 cents/kilogram).

Another, collaborative research program in Cameroon has been with the (U.S.) National Cancer Institute, and concerned *Ancistrocladus korupensis*, a plant that showed promising anti-HIV potential. This program has apparently served to demonstrate to the Cameroon government the need to review its bioprospecting policies: in 1993, three interministerial committees were created to study the issue. In 1994 the question was passed to the Prime Minister's Office, with apparently little progress. In May, 1994 a new interministerial committee was created specifically on the conservation and economic exploitation of *A. korupensis*, with the Chair hoping to formulate general policy recommendations on the regulation of all natural products research in the country.⁶⁷

The end of the report outlines several policy options for the Government of Cameroon, including incorporating the use of Material Transfer Agreements with existing permits. The Agreements could:

- define the permitted scope of research on the samples shipped abroad;
- stipulate that Cameroon retains the rights to commercialization and sale of products derived from the samples; or
- specifically prohibit commercial research on the samples (although the report notes that this latter alternative is not recommended because of difficulties in

⁶⁷ While the National Cancer Institute now has a standard Letter of Collection (Letter of Intent), in which the NCI offers a package of shared benefits, including royalties from subsequently developed marketable drugs, this was only prepared and in use after completion of the initial plant collections in 1988. The Letter was provided to the Cameroonian government for comment and approval, but no response was received by NCI. This letter is discussed at greater length below, in the section on Indonesia.

- distinguishing commercial research from academic research that leads to "commercializable" products); and
• provide for the sharing of benefits.

A long-term solution, it was noted, would develop a mechanism to encourage strategic alliances with commercial research firms. The Government could play a role by establishing guidelines by which to judge such deals in a fair and transparent manner.

With respect to intellectual property rights, both BDCP and international NGOs have expressed "considerable interest" in the intellectual property of local and indigenous groups' knowledge for medicine, agriculture, and the like. A proposed strategy to protect this would include passage of a national trade secrets law, sufficiently broad to encompass such knowledge, and to provide standing to local communities to sue for misappropriation by outsiders. It was noted that this would avoid the establishment of a registration system for such claims.

Another strategy noted is the creation of a patent-like or plant variety protection-like system for registration and protection (and disclosure) of this knowledge, as proposed for the protection of traditional agricultural genetic resources in India. This would, however, require a new and expensive bureaucracy.

Any of these alternatives would nevertheless require that the onus of prosecuting claims fall upon Cameroonians, who may not be in a position to bear the expense or time delays. Accordingly, the report suggests it may be more cost effective to carefully regulate access to the genetic resources at the collection end.

(c) The Gambia

In 1994, The Gambia enacted the *National Environment Management Act, 1994* (Law No. 13/94), authorizing the competent national authority to prohibit or restrict trade or traffic in any component of biological diversity. The law asserts that "the genetic resources of The Gambia shall constitute an essential part of the natural wealth of resources of the people of The Gambia," and authorizes regulations and guidelines for access to the genetic resources. These terms are explicitly to regulate the export of germplasm; the sharing of benefits derived from germplasm originating from The Gambia; and fees to be paid for access to germplasm. (Biodiversity Convention Secretariat Report, 1995)

This legislation is potentially very broad. While apparently limited to the physical resource (except for the possibility of requiring sharing of benefits derived from the physical germplasm, which would likely include benefits from intellectual property rights derived from the germplasm), the authorization to regulate trade or traffic in any component of biological diversity could be applied very broadly. Its scope would depend on the meaning given to the term "any component of biological diversity." This remains to be seen as the regulations and guidelines are drafted and then applied.

(d) Adoption of an INBio-Type Model for Africa

Calestous Juma⁶⁸ and Bernard Sihanya considered the feasibility of seeking to replicate the Costa Rican example of INBio elsewhere, and particularly in Africa. (Juma, 1993 in Reid, 1993) They concluded that, "To the extent that INBio represents a unique convergence of historical and institutional factors that makes acquiring scientific and technological capacity, as well as the required managerial and organizational skills, easier than it will be in many developing countries, it can't be readily replicated, and its 'learning-by-doing' approach may be glacially slow in many countries of the South. There is also the danger that an INBio for each country which houses biological resources may lead to competition among the source countries and lower the benefits." [It may be noted that, notwithstanding this recognized possibility, INBio has in fact hosted delegations to African and other countries for workshops on biodiversity prospecting, including genetic resources management.]

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⁶⁸ Dr. Juma was recently (August 1995) appointed Executive Secretary for the Convention on Biological Diversity.

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(This book is a synthesis of papers presented, and the subsequent discussions, at two events in Nairobi in 1991, one an African Regional Consultation on the Biodiversity Conservation Strategy Programme of the World Resources Institute, the World Conservation Union and UNEP, and the other an expert workshop on Property Rights, Biotechnology and Genetic Resources. The events provided input into the UNCED in Rio, 1992.)

Mugabe, 1994: John Mugabe, "Technology and Biodiversity in Kenya: Technological Capabilities and Institutional Systems for Conservation," in Krattiger, McNeely et al., *Widening Perspectives on Biodiversity* (IUCN 1994).

(This paper provides an in-depth analysis of the Kenyan institutions engaged in biodiversity conservation: the Kenya Wildlife Service (KWS), which while of recent origin has succeeded in establishing significant and formal institutional partnership arrangements explicitly based on sharing and acquisition of techno-scientific knowledge and expertise; and the National Genebank of Kenya (GBK), which lacks the institutional autonomy, authority and of the KWS, and has been unable to establish formal and elaborate partnerships. Mugabe argues that institutional capacity building should form a major focus of policy discourse.)

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(This report summarized the results of a two-week fact-finding assignment in Cameroon on the state of bioprospecting and biodiversity property rights legislation, in response to a request from the government for technical assistance in designing a new policy regulating biodiversity prospecting in Cameroon.)

4.5 India

4.5.1 Background

Resources

India's biodiversity has been characterized as one of the most significant in the world. Some 45,000 wild species of plants, and over 77,000 wild species of animals have been recorded, comprising about 6.5% of the world's known wildlife. This is, nevertheless, estimated to be only a fraction of India's wild biodiversity, since a number of biologically rich areas have yet to be fully explored. However, at least 10% of the recorded wild flora, and possibly a larger percentage of its wild fauna, are threatened as a result of deforestation, pollution, building and cultivation, habitat destruction, and over-exploitation. (Kothari, 1994a.)

Intellectual Property Framework

Traditionally, India has adopted firm positions opposing the grant of patent rights that restrict the ability of a developing country to obtain and use sophisticated technologies, or that relate to food, health or medical care (eg, pharmaceuticals, agricultural chemicals). Thus the Indian Patent Act of 1970 did not permit the grant of patents for substances in the fields of agriculture, horticulture, or curing or enhancing human, animal or plant life. (Kothari & Singh, 1994) Indeed, India was notable for its refusal to adhere to the Paris Convention, despite its accession by over 100 countries around the globe.

At the same time, India has one of the world's largest plant breeding enterprises in the public sector, the Indian Council of Agricultural Research and Agricultural Universities. This has created pressure to revise the Indian position, as some have argued that "action to protect the products of this research is urgently needed." (Swaminathan, 1994)

Today, the question whether particular biotechnology inventions are patentable under Indian law is unclear. The Patent Office takes the position that such inventions, especially live organisms, are not patentable. Processes for manufacturing non-living substances using micro-organisms in the process, have been patented. (Anand, 1995)

The most significant recent pressure on India's intellectual property system has come from first the negotiation of the TRIPs Agreement and now, since India signed the WTO Accord, the need to implement it.

TRIPs has been mired in controversy in India since it was first discussed. This was exacerbated when a patent was granted to Agracetus for its infamous Trans-Genic Cotton Cells.⁶⁹ In response to public pressure, last October the Government exercised its power under the Patent Act to revoke the patent on the ground that "a patent or the mode in which it is exercised is mischievous to the State or generally prejudicial to the public". Such a power has been used only once before by the Indian Government -- in 1961, to revoke a patent for a drink which was considered injurious to health.

The grounds for the revocation stated in the "show cause" notice were that cotton, as an important national crop vital to the export economy, should not be the subject matter of a patent; that the interest of farmers would be prejudiced; and that the effect of the patent when used was not known, and the cotton or oil could prove harmful. (Anand, 1995)

The controversy over changes to India's Patent Act continue. This year, the Government tried unsuccessfully to introduce amendments to the Patent Act, in order to implement its obligations under the TRIPs Agreement. This is discussed in greater detail below.

As of January 1, 1995, India had not adhered to either UPOV 1978 or 1991. However concern has been expressed that by failing to have a protection system for the work of Indian plant breeders (which is extensive -- according to one writer, over 90% of the crop varieties grown in India are the result of the research carried out in State Agricultural Universities and Research Institutes of the Indian Council of Agricultural Research), this work will be available free to others, while Indians find themselves paying royalties for what they obtain from elsewhere. (Swaminathan, 1994.) India's accession to the WTO has also exerted pressure to amend its intellectual property laws, to bring them into conformity with the TRIPs provisions. With respect to plant variety protection, TRIPs does not require adoption of UPOV standards, but rather provision "for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof." (Art. 27(3)(b)) (The provisions of that sub-paragraph are to be reviewed four years after the Agreement's entry into force.)

Accordingly, there have been discussions concerning an appropriate *sui generis* system for adoption by India. A prominent writer on plant protection issues, M.S. Swaminathan, noted that any such legislation would have to recognize the magnitude of the dependence on small farming holdings within India (over 70% of the population depend on agriculture for jobs and income). It would have to "be based not only on a consideration of economics, but also of ecology, equity and employment. It has to be pro-nature, pro-poor and pro-women". It should retain the breeder's exemption, strengthen the farmer's privilege, and provide an implementable mechanism for giving operational content to the concept of farmer's rights. (Swaminathan, 1994)

⁶⁹ This controversial patent is currently under review in the United States, because of its excessively broad scope.

Participants at an interdisciplinary dialogue held in January, 1994 in Madras sought to accomplish this, in preparing a proposed "Plant Varieties Recognition and Rights Act." (Swaminathan, 1994) The Madras Draft would provide incentives to breeders and farmer-innovators for undertaking certain breeding activities, establishing a Community Gene Fund from the sale proceeds of seeds of improved varieties, which would go to support farm/tribal men and women. At the meeting, participants proposed that 5% of the gross income from sales of new seed varieties be returned to rural innovators. (Swaminathan, 1994; Crucible Group, 1994; also discussed, 1994 Asian Round Table, below.)

The Crucible Group noted that, "If brought into law, this will be the first time that any country has legally acknowledged Farmers Rights. That the Government may adopt both Farmers' Rights and Plant Breeders' Rights in the same legislation will fuel the fires of debate from New Delhi to Geneva. The Indian initiative will become an important precedent for other countries." (Crucible Group, 1994, p. 35)

Other International Conventions

As noted above, India is a member of the World Trade Organization. It has also ratified the Biodiversity Convention.

4.5.2 Current Ideas, Approaches and Activities

(a) Proposed Block of Access

On April 23, 1995, the New York Times reported that India had threatened to block United States access to medicinal plants and other biological material, unless it ratified the Biodiversity Convention within three months.⁷⁰ The article quoted the Indian Environment Minister, Kamal Nath, as saying: "We cannot wait forever, and we do not want to be pushed into any corner. But if the ratification does not take place in the next three months, then obviously we must prevent other countries from taking advantage of the benefits accruing from our genetic material...The mega-diverse countries of Latin America, South and Southeast Asia are waiting for India to take the lead. If we do not have progress this summer then we will meet to map out a joint strategy on the transfer of genetic material."

The report stated that the Indian position has support from countries including Brazil, Indonesia and Malaysia. However, it may be noted that the article also suggests the Indian position may be a tactic in a dispute with the United States over Indian difficulties in obtaining Parliamentary passage of an intellectual property clause in the WTO Agreement, discussed below under (b). Just as President Clinton has signed the Biodiversity Convention but been unable to secure its ratification

⁷⁰ Sanjoy Hazarika, "India Presses U.S. to Pass Biotic Treaty," *New York Times*, April 23, 1995, p. 13.

by the Congress, now Republican-controlled, so the Indian Government, which signed the WTO, has been unable to secure passage of the intellectual property implementation provisions through its Parliament, where it is in a minority. The New York Times quoted a senior Indian official as saying, "This is not a trade-off for the other side's ratifying the Biodiversity Convention, but clearly this is not a one-way street."

(b) Proposed Amendments to the Patent Act

(Except where otherwise noted, the following is based on reports contained in Shiva, 1995.)

As noted above, the Indian Patents Act of 1970 does not presently permit patenting of substances in the fields of agriculture, horticulture, and curing and enhancing human, animal or plant life. (Kothari & Singh, 1994) Concerns have been expressed about the pressure within the international community to dilute or indeed prevent the existing relatively free access to plant genetic resources; for example, the acceptance by the FAO of the compromise formulations of Farmers' Rights and Breeder' Rights. Proposals have been made that India should respond by creating a legal structure ensuring free access, and providing also some form of incentives and rewards for those with traditional or new knowledge relating to biodiversity and biotechnology. (Kothari & Singh, 1994)

However India's signing of the WTO carried obligations to amend the Patents Act, to bring it into conformity with the TRIPs Agreement. A Patents (Amendment) Ordinance, 1994 was issued by the government, to effect these amendments. In particular, it would have introduced "exclusive marketing rights" for "medicines and drugs"; under the 1970 Act, "medicine and drugs" is defined very broadly, to encompass human and animal medicines; insecticides, germicides, fungicides, weedicides and all other substances intended to be used to protect and preserve plants; all substances intended to be used to maintain public health or prevent and control human and animal disease; and all substances intended to be used in the diagnosis, treatment, mitigation or prevention of human and animal diseases. Thus, the amendments would have significantly reversed Indian policy on agricultural and health products.

The changes required by TRIPs have been controversial. One writer reported, "The Indian streets and Parliament have been rocked by protests related to TRIPs and changes in the Indian patent laws ever since the Dunkel Text of the GATT treaty was finalized in December 1991. Farmers held national rallies with up to half a million protesters in Delhi and Bangalore; all opposition parties held rallies and public meetings when the GATT treaty was being signed in Marrakesh." (Shiva, March 22, 1995)

The amendments were presented by the Government in a manner that even a supporter of the changes described as "unethical, undemocratic and also unwise." (Gupta, 1995) In brief, the Government issued the Ordinance (Presidential Decree) on December 31, 1994, a week after the Parliament had closed its winter session. It argued that, "Since the [WTO] measures were to be brought into force with effect from 1st January 1995, in terms of our commitment in TRIPs

agreement, and as Parliament was not in session, the President promulgated the Patents (Amendment) Ordinance, 1994 (Ord. 13 of 1994) on the 31st December 1994."

The Government then pressed the implementing legislation, the Patent (Amendment) Bill, 1995 (No. 10 of 1995) through the Lok Sabha on a day when large numbers of Parliamentarians were absent for assembly elections, and attendance was unusually low. The Bill was passed by three votes.

In March, the Bill came for debate in the Rajya Sabha, the Parliament's Upper House, where the Government is in a minority position. On March 22, that House forced the government to defer the bill indefinitely. Since the Ordinance needed to be voted in Parliament within 90 days of its issue in order to become a permanent part of Indian law, the Ordinance has now lapsed.

(c) Current Regime for Access to Genetic Resources

(i) 1992 Report

At the request of the Ministry of Environment and Forests of the Government of India, a report entitled *Legal Provisions Relating to Biodiversity in India* was prepared and circulated in June 1992. The report reviewed existing legislation, constructed a conceptual framework within which to review that legislation, and made recommendations. The findings and recommendations are presented by the Project Director and Collaborator in an article, "Biodiversity and Indian National Law: A Conceptual Framework," (Kothari & Singh, 1994), the relevant parts of which are summarized below:⁷¹

There is currently no single, coordinated legislative framework governing access to and use of genetic resources. Individual provisions may be found in a variety of statutes -- governing such things as cutting notified species of wild flora, exporting notified species (eg, until 1993, parts and derivatives of wild plants were on the list of items notified under the export legislation; this has now been removed). The study found that identification, which is a prerequisite for protection, is not provided for in any law; *in situ* protection is not extended by law to domesticated flora and fauna, nor to seeds; while a number of *ex situ* collections exist, there is no legislation in place governing the protection of the biodiversity of such collections.

Access to and extraction of genetic materials seems to be regulated only insofar as they constitute "property", and the use and taking of property is addressed under general property law. (Kothari & Singh, 1994)

⁷¹ It may be noted that there were certain laws and rules that were excluded from the scope of the study, such as state legislation (the study only noted national legislation), and laws of indirect relevance. A more comprehensive study filling in these gaps was recommended, and undertaken by the Centre for Environmental Law of the World Wide Fund for Nature (India). (Kothari & Singh, 1994)

(ii) Current Status

This consultant was advised by an official with the Ministry of Environment and Forests that a proposal of a system of regulation of access to genetic resources is in the preliminary stages of preparation. No legislation has yet been introduced on the subject, and the substance of the proposal is still confidential.

Private agreements have not yet been relevant for issues or terms of access.

(d) The USAID-India Agreement

In 1988, the United States Agency for International Development (USAID) concluded an agreement with the Government of India whereby USAID would provide \$13 million to India to set up a genebank and related facilities. The facilities would be maintained by the Indian National Bureau of Plant Genetic Resources (NBPGR). The stated goal was that by September, 1995, a comprehensive inventory will have been completed of nearly 121 germplasm collections, a computerized germplasm database management system will be in place, "and plant germplasm will be readily available for research purposes to scientists in the public and the private sector in India and worldwide." (Agreement, quoted in Menon, 1995)

This agreement has been criticized by several commentators for its failure to provide any commitment by the United States to provide access to genetic materials or other benefits derived from the germplasm collected within India. (Kothari, 1994b, citing a 1992 article by Menon; and Menon, 1995.) Similarly, no limits are placed on the use of the materials, so that foreign researchers are free to patent any material derived from the genetic materials, and withhold such material from Indians and others. (Kothari, 1994b and Menon, 1995)

(e) The Third World Network Draft Community Intellectual Rights Act

The Third World Network has prepared a draft *Community Intellectual Rights Act*, to provide for the protection of indigenous and local community rights.⁷² The draft is examined in greater detail in the companion literature review by Howard Mann. However, a brief summary of its proposals is appropriate here.

The stated purpose of the proposal is to create an alternative to the traditional intellectual property system -- an alternative specifically designed to address the obstacles currently faced by indigenous and local communities in claiming rights in their knowledge and resources.

⁷² The Third World Network has also prepared a proposed Collector's Act, and a Model Contract Between Collectors and the Nation State. Unfortunately, we were unable to obtain copies of these latter two documents in time for this study.

The proposal does this in fundamentally two ways. First, it defines "local community" very broadly: "a group of people having a long standing social organization that binds them together whether in a defined area or howsoever otherwise and shall include indigenous peoples and local populations." This definition is thus based in social organizations, rather than commercial or economic ones.

The proposal then uses a very large definition of "innovation" to encompass virtually all knowledge -- and it is notable that this already broad definition is open-ended. It states:

"innovation" shall include any collective and cumulative knowledge or technology of the use, properties, values and processes of any biological material or any part thereof rendered of any, or enhanced, use or value as a result of the said cumulative knowledge or technology whether documented, recorded, oral, written or howsoever otherwise existing, including any alteration, modification, improvement thereof and shall also include derivatives which utilize the knowledge of local communities in the commercialisation of any product as well as to a more sophisticated process for extracting, isolating or synthesizing the active chemical in the biological extracts or compositions used by the local communities.

The proposal goes on to declare the local community to be the lawful and sole custodians and stewards of an innovation "at all times and in perpetuity." It expressly prohibits grants of "any exclusive monopoly" in respect of innovations, and any assignments or dealings with innovations "whereby the status of the local community as custodians and stewards of the innovation or the integrity of the innovation, is impaired."

Article 1.3 declares that "any impairment of the right to the innovation shall be void as against the local community." Thus, any attempts even by a local community to grant rights which are found to impair the status of the local community as custodian and steward -- the meaning of which is unclear -- are declared to be void.

The proposal anticipates commercial use of innovations, and stipulates that the written consent of the local community must first be obtained, and the local community receive a minimum percentage of the gross sales of any product or process incorporating the innovation, or a non-monetary equivalent as determined by the local community.

The section stipulates that, "Nothing in this section shall prevent more than one person, body, organization or corporation from using any innovation or any part thereof for commercial utilisation and at the same or any other time." It is unclear whether this is simply repetitive of the earlier prohibition against grants of exclusive monopolies in respect of innovations, or whether by the limitation to "nothing in this section shall prevent..." the section leaves open the possibility of individual agreements providing for exclusive rights. In this connection, it may be noted that the proposal anticipates situations where more than one community have rights to an innovation, and the proposal establishes co-stewardships for this situation.

Finally, the proposal anticipates establishment of a voluntary registration system both for local communities, and for innovations. The systems are to be voluntary; failure to register would in no way prejudice any rights under the Act.

While the proposal contains a number of interesting approaches to recognizing and rewarding indigenous and local communities for their knowledge and resources, the sweeping scope of rights that would be granted under this proposal make it unfortunately vague and difficult to apply with any certainty. By its terms, it would appear to try to make it impossible for anyone to claim intellectual property rights in anything obtained from or based upon the broadly-defined "innovation" -- which presumably would act as a strong deterrent to anyone seeking rights to such innovations.

(The above is based on a review of Nijar, Biodiversity Convention Briefings.)

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(This paper is a comprehensive review of Indian legislation relevant to biodiversity, and includes analysis of existing loopholes and suggestions of ways to close them.)

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Swaminathan, 1994: M.S. Swaminathan, *A Plant Variety Protection System for India*, Working Paper No. 2, February, 1994 (Centre for Research on Sustainable Agricultural and Rural Development).

Asia

4.6 General: The Manila Declaration

In February 1992, 283 scientists from 31 countries attended the Seventh Asian Symposium on Medicinal Plants, held in the Philippines. At the end of the symposium, they issued a declaration (known as "the Manila Declaration"), expressing their concern that the exploitation of biological resources and indigenous knowledge had worked to the disadvantage of developing nations in the region.

The Declaration recommended that national governments develop legislation to control the collection and export of biological material. (It may be seen that this Declaration, which slightly predated the signing of the Biodiversity Convention, recognized that national governments have sovereignty over their biological resources.) Specifically, the Declaration recommended that access agreements for collection of biological resources include provisions regarding any subsequent commercial development that may arise, and establish mandatory royalty or license agreements to ensure fair and equitable distribution of benefits to the region of origin. In addition, it proposed that "the traditional knowledge of local participants contributing to the development of new natural products must be recognized *as significant intellectual property*". (emphasis added)

Appended to the Declaration was a Code of Ethics for Foreign Collectors of Biological Samples, originally developed at a workshop in Australia and modified in April 1992 to cover other biological material. That code directs foreign collectors on specific procedures and standards to observe, to ensure that the collection is accomplished in a manner that respects the sovereignty of the country over its biological resources, and does not have deleterious effects on the conservation and maintenance of biodiversity.

4.7 The Philippines

4.7.1 Background

Resources

As described by Marvic Leonen and Antonio G.M. La Vina, the Philippine terrestrial ecosystems "include some 8,000 species of indigenous flowering plants, 3,000 of which are trees, and 4,000 species of pteridophytes, bryophytes, fungi, algae and lichens. More than 2,500 species of wild fauna, excluding insects and invertebrates, can be found on more than 7,000 islands. These include 196 species of mammals, up to 975 species and sub-species of reptiles, and the same number of species and sub-species of birds. Plant endemism is estimated at 44%, while that of animals is estimated at 43% of species." (Leonen and La Vina, 1994)

Under the Regalian Doctrine, which is central to Philippine management of natural resources, all natural resources belong to the state, and therefore private ownership or title must come from the state. This is expressed in the Philippine Constitution, which provides that all "lands of the public domain, waters, minerals, coal, petroleum, and other mineral oils, all forces of potential energy, fisheries, forests or timber, wildlife, flora and fauna, and other natural resources are owned by the State. With the exception of agricultural lands, all other natural resources shall not be alienated." (Leonen and La Vina, 1994)

Intellectual Property Framework

The Philippines is a party to the Paris Convention. As of January, 1995, it was not a party to either version of UPOV.⁷³

The Philippine Patent Law grants patents on "any invention of a new and useful machine, manufactured product or substance, process, or an improvement of any of the foregoing." An invention is not patentable "if it is contrary to public order or morals, or to public health or welfare, or of it constitutes a mere idea, scientific principle or abstract theorem not embodied in an invention, or any process not directed to the making or improving of a commercial product."⁷⁴ As will be discussed below, the recent 1995 Philippine Executive Order suggests that new intellectual property laws will be forthcoming. It may be expected then that these laws may be revised in the near future.

Other International Conventions

The Philippines is a member of the World Trade Organization, and it has ratified the Biodiversity Convention.

4.7.2 Current Ideas, Approaches and Activities

(a) The 1995 Philippine Executive Order

On May 18, 1995, the President of the Philippines took steps to implement Article 16 of the Biodiversity Convention by issuing Executive Order No. 247, which prescribes guidelines for bioprospecting for scientific and commercial purposes.

⁷³ Unfortunately, we have been unable to ascertain with certainty whether the Philippines provides any plant breeder right protection. No such legislation is referred to in any of the Philippine intellectual property law digests we reviewed in preparing this study.

⁷⁴ Republic of the Philippines, Revised Rules of Practice and Patent Act. (The English translation was obtained from: John P. Sinnott, *World Patent Law & Practice: Patent Statutes, Regulations and Treaties*, Vol. 2H, "Republic of the Philippines".)

The Order begins with the assertion that, as a matter of Philippine constitutional law, wildlife, including flora and fauna, are owned by the State, and the disposition, development and utilization thereof are under the State's full control and supervision. It then establishes an Inter-Agency Committee on Biological Resources, including representatives from the government departments responsible for the conservation, management and sustainable development of the environment and natural resources; science and technological development; agriculture; health; and foreign affairs, as well as academics from the Philippine science community, representatives from a non-governmental organization active in biodiversity protection, and a representative from a People's Organization made up of indigenous communities and organizations. This Inter-Agency will be responsible for reviewing and making recommendations on applications for a collection agreement, as well as monitoring compliance with the Executive Order and the agreement. It may be noted as well that the Inter-Agency is specifically directed to study and recommend appropriate laws on the utilization of biological and genetic resources "including new laws on intellectual property rights." (Section 7(f)) It would seem likely, then, that revision of the intellectual property regime is anticipated by the Government.

The Order establishes an interesting regime governing access to genetic resources. The expressed Policy of the State is to regulate the prospecting of biological and genetic resources "so that these resources are protected and conserved, are developed and put to the sustainable use and benefit of local capability in science and technology to achieve technological self-reliance in selected areas." (Section 1)

It then proceeds immediately to protect the rights of local and indigenous communities by allowing prospecting within the "ancestral lands and domains" of indigenous communities only with the prior informed consent of the community concerned, obtained in accordance with its customary laws; and with respect to local communities, only with its prior informed consent. (Section 2) The Order establishes procedures requiring that research proposals be submitted to the recognized head of the local or indigenous communities that may be affected. It then provides that, "Action on the proposal shall be made only after 60 days has lapsed after a copy of the proposal is received by the persons concerned." (Section 4)

This would seem to establish a "negative presumption," that is no comment is deemed approval by the indigenous or local community. This may be contrasted with one of the regimes proposed for adoption by the Andean Pact countries (discussed above). That would have provided that silence would be construed as refusal; a positive acceptance of the request was required from the local/indigenous community, before an application could be acted upon.

However it is unclear whether in fact this is the approach anticipated by the Order. As mentioned, the Order requires "prior informed consent". It also directs the Inter-Agency to "ensure that the right of the indigenous and local communities wherein the collection or researches are being conducted are protected, including the verification that the consent requirements in Sections 3 and 4 are complied with. The Inter-Agency Committee, after consultations with the affected sectors, shall formulate and issue guidelines implementing the provisions on prior informed consent." (Section 7(c))

All prospecting of biological and genetic resources (other than traditional uses of biological resources by indigenous and local communities) is to be done pursuant to a Research Agreement concluded with the government. If the research and collection is intended "directly or indirectly" for commercial purposes, then a Commercial Research Agreement must be concluded; if for academic purposes, then an Academic Research Agreement is required. It is interesting that only Philippine entities and "intergovernmental entities" may apply for an Academic Research Agreement.

The Order stipulates that "all Research Agreements with private persons and corporations, including all agreements with foreign *or international entities*, shall conform with the minimum requirements of a Commercial Research Agreement." (Section 3, emphasis added) As drafted, given the breadth of the Order, this would appear to include collections that previously would have come within the FAO 1983 Undertaking, unless the agreement falls within the limited parameters allowed for Academic Research Agreements. This demonstrates the government policy of encouraging the use and development of local capability in science and technology.

The Order sets out minimum terms for both Commercial and Academic Research Agreements, as follows:

- there must be a stated limit on samples that may be obtained and exported, and a statement that the approved list and amount of samples must be strictly followed;
- a complete set of all specimens collected must be deposited with the National Museum or other designated government entity;
- access to collected specimens and relevant data shall be allowed to all Filipino citizens and to Philippine governmental entities whenever these specimens are deposited in depositories abroad;
- the collector or, where appropriate, its Principal, must inform the Philippine Government and any affected local and indigenous community of all discoveries from the activity conducted in the Philippines, if a commercial product is derived from the activity;
- provision must be made for the payment of royalties to the national government, local and indigenous community and individual person or designated beneficiary, if commercial use is derived from the biological and genetic resources taken. Where appropriate and applicable, other forms of compensation may be negotiated;
- the agreement must provide for unilateral termination by the Philippine government in the event any of its terms have been violated, or "on the basis of public interest and welfare";

- status report on both the research and the ecological state of the area and/or species involved must be regularly submitted to the Inter-Agency;
- if the Commercial Collector or its Principal is a foreign person or entity, the agreement must provide for the active involvement of Philippine scientists in the research and collection process and, where applicable and appropriate as determined by the Inter-Agency, in the technological development of a product derived from the resources. This involvement is to be paid for by the Commercial Collector;
- the Commercial Collector and/or its Principal are to be encouraged to use the services of Philippine universities and academic institutions. Where appropriate, the Commercial Collector and/or its Principal are to be required to transfer equipment to a Philippine institution or entity;
- a fixed fee is to be paid to the Department of the Environment and Natural Resources, according to a schedule set by the Inter-Agency;
- in the case of endemic species, the Agreement must include a statement that the technology is to be made available to a designated Philippine institution, and may be used *commercially and locally* without payment of royalties to a Collector or Principal. The Order adds that "where appropriate and applicable, other agreements may be negotiated."
- the maximum term for a Commercial Research Agreement is three years, ~~renewable~~ upon review by the Inter-Agency. (Section 5)

The Order also requires that any Commercial or Academic Collector who is "merely an agent or merely collecting for another person or entity", must submit the agreement between the Collector and that other person or entity, for review by the Inter-Agency "to determine the latter agreement does not undermine the substantive requirements of this Executive Order." (Section 3)

Additional provisions are set out for inclusion in Academic Research Agreements, anticipating that they will be drafted more broadly and generally than the commercial ones, and that the fee to be paid to the Philippine Government will be a minimal one. Again, it is specified that "the university institution or government entity must ensure that affected communities have given their prior informed consent to the activities to be undertaken." (Section 5(m)) A provision must also be included requiring the Academic Collector to apply for a Commercial Research Agreement "when it becomes clear that the research and collection being done has commercial prospects." (Section 5(n)) The maximum term for Academic Research Agreements is five years, again renewable upon review.

Violation of the Order is sanctioned by criminal penalties; failure to comply with the terms of the Research Agreement "shall be a valid cause of immediate termination of the Agreement and the imposition of a perpetual ban on undertaking prospecting of biological and genetic resources in the Philippines." (Section 10)

In conclusion, the regime established by this Order would appear to be modelled significantly on the INBio precedents, with provision for both payments "up front" to the Department of the Environment and Natural Resources, and for royalty payments. There are extensive mechanisms included to ensure the development of scientific and technological capability within the Philippines, including transfer of technology requirements.

The strong conditions placed on commercial and research agreements may as a practical matter create too high a risk for bioprospectors. In particular, the potential for unilateral termination "on the basis of public interest and welfare" may be found to create too much uncertainty. However, in general the Order was received by the Biodiversity Convention Secretariat as perhaps the "most noteworthy" of recent national developments in implementing the Biodiversity Convention. The Secretariat reported that the Philippines is currently in the process of formulating implementing regulations. (Biodiversity Convention Secretariat Report, 1995.)

The Order anticipates the payment of royalties, which presumably would result from intellectual property rights. Otherwise, intellectual property rights do not appear to be addressed yet, although as noted the Order directs the Inter-Agency to propose appropriate laws. The one exception is contained in Section 5(1), allowing for the free commercial use of technology; in effect, a form of compulsory licensing. It is interesting that this is the only provision that allows for alternative arrangements to be made upon agreement.

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4.8 Indonesia

4.8.1 Background

Resources

Indonesia has been described as a "mega-diversity country": 17% of the total number of species in the world are endemic to the country, although Indonesia occupies only 1.3% of the earth's area. However, its policies on biodiversity are still noted by some to be on the periphery of policy agendas, subordinated to the support of development, science and technology. (Santoso, 1994; Asian Round Table, 1994, where it was argued by an Indonesian NGO that "however important information on sustainable utilisation is, it is only through income improvements that conservation can be achieved.")

The Fifth National Five-Year Development Plan, covering the period 1989/90-1993/94, refers to biodiversity in the context of germplasm. The outline of the Sixth Five-Year Plan states: "Conservation of national forests, including their flora and fauna and their natural uniqueness, shall be improved to preserve the diversity of germplasm, species and ecosystems. Research and development of potential utilisation of forests for the sake of national welfare, especially for the development of agriculture, industry and health, shall be improved. Inventorying, monitoring and accounting of the value of natural resources and environment shall be promoted for ensuring their utilisation." (Santoso, 1994)

In contrast to Western countries, where environmentalism has moved from the "grassroots" to policy by means of popular pressure brought to bear on governments, environmentalism in Indonesia has been characterized by the reorientation of government policy; popular pressure, especially from NGOs, exists but is relatively weak. (Santoso, 1994)

Intellectual Property Framework

With respect to intellectual property rights, Indonesia is a party to the Paris Convention, but not to UPOV; it has a patent law, and a law relating to cultivated plants⁷⁵, but no provision at present for plant breeders' rights. (Satrapradja, 1995) Its patent law is relatively new; it came into force in 1991, almost two years after its promulgation, and 36 years after it was promised. (Gautama, 1993) The Act prohibits patents for inventions "on a production process or product of food and drink(s), including products in the form of raw material made by chemical processes with the aim to produce food and drink for human and for animal consumption; an invention on a new

⁷⁵ The writer was unable to obtain a copy of this law; it is unclear what it protects or permits.

species or variety of plant or animal or any other process that can be used to cultivate plants or animals, including products thereof."⁷⁶

Studies have noted that the existing patent law framework in Indonesia is insufficient to provide the needed policy direction on the issue of genetic resources and the development of new biotechnologies in Indonesia. (Lagos-Witte, 1994)

Other International Conventions

Indonesia is a member of the World Trade Organization. As of May 1995, it had signed the Biodiversity Convention, but not otherwise ratified it.

4.8.2 Current Ideas, Approaches and Activities

(a) Access to Genetic Resources: LIPI Rules and Procedures

The current regulation of access to genetic resources is found in the Rules and Procedures Governing Permission from the Government of Indonesia for Foreign Researchers to Conduct Research in Indonesia, issued by the Indonesian Institute of Science (LIPI). While these remain in effect, in fact they are often ignored, and access is determined under terms of more recent agreements, for example ones with universities or the United States National Cancer Institute (NCI), discussed below. (Satrapradja, 1995)

One of the stated objectives of the LIPI rules is to ensure that knowledge gained about Indonesia through research, is made available to the Indonesian people. The rules themselves contain several interesting provisions. First, they require that foreigners intending to do research in Indonesia must first obtain permission from LIPI, before a visa will be granted. Second, the mandatory conditions include, "The rights to findings and copyright of the research results shall be established in agreement with LIPI," (s. 3.6), and "A special agreement has to be signed for specimens/samples studied or collected in the course of the research." (s. 3.7) Finally, section 6.5 states:

No foreign researcher may take out of Indonesia any articles or materials whose export is prohibited by Indonesian law, unless he has first obtained written permission from the institution which has the legal authority to permit their export. **In principle, all specimens/samples are Indonesian property**, although in some cases they may be borrowed. **Duplicates may sometimes be kept abroad, based on prior agreement with the Indonesian Government.** (emphasis added)

⁷⁶ Law of the Republic of Indonesia No. 6 of 1989, Concerning Patents, Article 7. (The English translation was obtained from: John P. Sinnott, *World Patent Law and Practice: Patent Statutes, Regulations and Treaties*, Vol. 2E, "Indonesia".)

This is reinforced in the standard agreement on collection of samples, attached to the LIPI rules, which adds, after reiterating that the specimens remain the permanent property of the Government: "The undersigned [researchers] acknowledge a moral obligation to the fullest extent of their ability, even after return to their laboratories."

These rules therefore lay the foundation for requiring full informed consent. The rules and standard agreement are clear as to ownership of the physical specimens; s. 3.6 arguably could be used as a basis for a position that ownership of any intellectual property rights arising out of the research results, must be the subject of negotiation with LIPI. It is unknown whether these rules have been used in this way -- there is no reference to any such use in the literature reviewed. However, arguably the foundation exists for Indonesia to assert rights in the specimens, and in intellectual property rights that may arise therefrom.

(b) Access to Genetic Resources: The NCI Plant Collection Program in Indonesia

The NCI has been involved, through U.S. contractors (the University of Illinois) and sub-contractors (the Arnold Arboretum of Harvard University) in a collaborative plant collection program in Indonesia for over 5 years.⁷⁷ This has resulted in the deposit of more than 5,000 high quality herbarium specimens at the designated Indonesian Research and Development Centre (the Herbarium Bogoriense). Because of the participation of local researchers, this project is considered to have strengthened the in-country capability to conduct inventories and identify the national flora, as well as facilitated the gathering of information about plant resources from isolated regions. (Lagos-Witte, 1994.) NCI financial investment in Indonesia was estimated at about \$100,000 over 5 years, 50% of which represented travel and other expenses for the counterparts at the Herbarium Bogoriense. Additional research grants were also provided by NCI to Indonesian senior scientists for their own research. (Lagos-Witte, 1994)

As Lagos-Witte emphasized in her report, the NCI contractors and sub-contractors are "working under the conditions of the NCI-screening program and have no influence on decisions concerning property rights or royalty sharing from any successfully developed marketable drug. Such decisions would apply to stages of development far past the stages of collecting and screening. The role of the Arnold Arboretum is the collection and identification of plant material. As a not-for-profit research institution, the Arnold Arboretum and Harvard University would gain nothing from any potential commercial application resulting from research in Indonesia. Rather, their vested interest is in developing and maintaining productive research relationships with Indonesian

⁷⁷ As of March, 1994, NCI had signed formal agreements with four developing countries to make best efforts to share benefits. NCI has one of the largest bioprospecting programs in the world: its annual budget is \$8 million (US\$); it has screened more than 23,000 samples from more than 7,000 plant species from 25 countries. (ANZECC, 1994)

counterpart institutions and contributing to conserving and sustainably using Indonesian biodiversity."⁷⁸

The relationship between Indonesia and the NCI is governed by the standard "Letter of Intent," formulated by the NCI. That Letter of Intent acknowledges in the preamble that, "NCI wishes to promote the conservation of biological diversity, and recognizes the need to compensate source country organizations and peoples in the event of commercialization of a drug developed from an organism collected within their borders."

Paragraph (5) provides that NCI will "as appropriate" seek patent protection on all inventions developed under the agreement by NCI employees alone or jointly with employees from the source country. Paragraph (8) provides that, if the agent is licensed to a pharmaceutical company for production and marketing, NCI, in consultation with the source country collaborator organization [notably, not the source country], will make its "best effort" to negotiate with the pharmaceutical company for inclusion of royalty payments to the source country collaborator, and/or groups and individuals of the source country who provided material and information.⁷⁹

The Letter of Intent also states that the NCI will require licence applicants to look to the source country as the first source of supply for natural products; if no such licensee is found, or the source country cannot fulfil the needs, the licensee will be required to pay the source country organization an amount of money, to be negotiated, "to be used for expenses associated with cultivation of medicinal plant species that are endangered by deforestation, or for other appropriate conservation measures."

It is interesting to note that none of these provisions apply to organisms "which are freely available from different countries (e.g., common weeds, agricultural crops, ornamental plants, fouling organisms) unless information indicating a particular use of the organism (e.g., medicinal, pesticide) was provided by local residents to guide the collection of such an organism from their country, or unless other justification acceptable to both the [source country organization] and DTP/NCI is provided." This is relevant both to issues of use of local and indigenous knowledge, and to the implications of *ex situ* collections of samples: because the term "freely available" does not specify "*in situ*", quaere whether an organism originally from Indonesia, but now, because of previous sharing and exchanges of specimens, is also available elsewhere, falls within this provision.

⁷⁸ One could take issue with Lagos-Witte's premise: increasingly, universities today actively pursue intellectual property rights, and licensing their patent rights to industry for commercial development. This is becoming a significant source of income for universities, and the desire to seek such income is likely only to increase given the severe financial constraints faced by universities these days.

⁷⁹ NCI, as an agency of the U.S. government, is prohibited by U.S. law from entering into agreements with other governments that legally bind a third party (eg, a private pharmaceutical company). "Best efforts" is apparently a legally demonstrable and enforceable term behind which NCI can "throw the full weight of the U.S. government against non-compliant third parties." (Lagos-Witte, 1994)

The Letter also obligates NCI to use, where possible, local and indigenous knowledge to guide the collection of organisms. It states that all such information will be kept confidential until both parties agree to publication: this lays the foundation for trade secret claims in such knowledge. However, no mention is made of compensation to the local or indigenous group for the knowledge. Instead, proper acknowledgement of the contribution is all that is expressly required.

It is interesting also to consider the terms of the standard Material Transfer Agreement used by the NCI and National Institute of Health (NIH) to provide plant extracts and microbial cultures, etc., from the Natural Products Repository for use in cancer and AIDS research. Paragraph 9 provides for the negotiation and payment of royalties to the original source country from any invention resulting from the use of the natural product, whether the invention is the actual isolated natural product, or a product structurally based on the isolated natural product, although the royalty rates and other compensation may vary. It also provides for the agreement to use the source country as the first source of supply of the product, or of any cultivation efforts required.

Paragraph 4 of the Agreement is of potential concern to trade secret claims by local and indigenous groups. That paragraph obligates the recipient of the extract, culture, etc., to treat as confidential any material received from NCI that is marked "CONFIDENTIAL", but only for a period of three years. Quare whether this applies to information obtained from local and indigenous groups, and if so, whether the NCI has any mechanism in place to ensure that such information is kept confidential unless and until the group agrees to its disclosure.

In her report, Lagos-Witte outlines a series of benefits and disadvantages to Indonesia arising out of the NCI arrangement. The benefits include: NCI bears the costs of collections and screening; Indonesia gets the benefits of a full duplicate of plant material collection, their identification and the results of their screening; all points for the Letter of Intent are open to negotiation, including compensation and royalty percentages; the potential exists for cooperation between Indonesia and NCI to facilitate alternative research and development programs; support of specialist training for Indonesian scientists and institutions is provided; and there is support in the development of other research programs related to biodiversity.

Some of the noted disadvantages are: Indonesian incentives to develop its own drug discovery industry are diminished; drug discovery is not resident in Indonesia; and drug patents and the prospect of direct profits from them do not accrue to Indonesia. Lagos-Witte notes that points of agreement to offset or compensate for these disadvantages can and should be negotiated.

(c) Access to Genetic Resources: Lagos-Witte Recommendations

At the end of her lengthy report, Lagos-Witte made a series of recommendations for the conclusion of a well-designed, functional policy regarding biodiversity property rights In Indonesia. These included:

- examination of Indonesian regulations and procedures that address rights over genetic resources and compensation for their availability to foreign parties, to ensure they recognize, in any compensation mechanism, local communities as parties to the contribution, and also to see that they are consistent with a model suitable for a South- South approach to the issue of biodiversity property rights;
- ensuring that Indonesian regulations and procedures address the strengthening of in-country capacity to develop product discovery and development programs, so as to provide more benefit from and control of Indonesian biodiversity. Technical training and transfer of technology agreements should be negotiated and maintained with institutions that can contribute to the advancement of Indonesian science.
- establishing a single governmental authority to negotiate and commit to agreements on the discovery and commercialization of plant-derived products, whether LIPI or another department, such as the Department of Health of the Ministry of Science and Technology. This will ensure a functional and consistent process of regulation;
- drawing on input from collaborations with local and international NGOs, universities, and private sector parties in evaluating the Indonesian position on biodiversity property rights and intellectual property rights, and proposed modifications and enhancements; and
- establishing or contributing to mechanisms for a consensus among developing countries around issues of biodiversity property rights based on the Biodiversity Convention, the Manila and Panama Declaration, the Oslo Declaration [of the Keystone Conference, discussed above at §3.8], and the items contained in the Global Biodiversity Strategy.

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4.9 Australia

4.9.1 Background

Resources

As is evident from the above discussion, there is usually a clear bifurcation between those countries that possess extensive biodiverse resources -- developing countries -- and those that possess the financial and technical means to use those resources in the biotechnology industry -- the industrialized, or developed, nations. This has resulted in the debate spilling over into the traditional political context of "North-South" relations.

Australia is an exception. Australia numbers among the dozen "mega-diverse" countries of the world that cumulatively account for approximately 60-70% of the world's global biodiversity. (CCST, 1994) Six families of mammals, six of birds, and twelve of flowering plants are endemic -- significantly more than any other country. At the species level, 90% of Australia's flowering plants, more than 80% of its mammals, 70% of its terrestrial birds, almost 90% of its reptiles, and 93% of its frogs are found only in Australia. (CCST, 1994)

Among the products that originated from Australian resources but now are produced elsewhere, are the macadamia nut (now extensively produced in Hawaii); several plant varieties marketed in the European and North American flower industry; the kangaroo apple, a shrub native to Australia and New Zealand, now grown on Russian plantations, from which particular steroids are produced; and several rainforest plants, such as *Castanospermum australe* (black bean), from which several potential anti-cancer drugs have been derived. (ANZECC, 1994; CCST, 1994) It has been estimated that the lost returns from these missed opportunities "would [no doubt] have amounted to many millions of dollars." (ANZECC, 1994, p. 9)

Australia is under increasing pressure from both domestic and foreign interests to provide access to Australian biological resources for research and development activities. Much of the interest has focused on the genetic resources of the Great Barrier Reef and the North Queensland rainforests, but interest is being expressed in the arid land species, as well. (ANZECC, 1994, p. 11)

At the same time, Australia is an industrialized nation that relies heavily on the import of genetic material for agricultural and forestry improvement, and has significantly increased the commercial value of introduced species by both selective breeding and genetic manipulation (eg, sheep, cattle wheat, sugar cane, plantation trees). (CCST, 1994) Indeed, Australian agriculture is almost wholly dependent on foreign germplasm. (ANZECC, 1994, p. 18) As is noted in the Australian Government report, "It therefore must be recognized that Australia has benefited by comparatively cost-free introduction of many foreign-sourced biological species. Any future arrangements on access to Australian biological resources should accommodate the need for the continuation of supplies of exotic genetic material." (CCST, 1994, p. 12)

Intellectual Property Framework

Australia also has a sophisticated regime for intellectual property protection. It is a member of both the Paris Convention and UPOV 1978. Its law provides patent protection for inventions or discoveries that involve the technical intervention of humans -- that is, patents will not be granted for something that occurs naturally -- so long as the requisite elements of novelty, inventive step and usefulness are satisfied. A patent can be obtained for inventions involving: living matter such as plants or animals (excluding human beings) and microorganisms; constituents of living matter, such as genetic material (DNA, genes); and products of such living matter (eg, drugs). (CCST, 1994, p. 24-26)

Plant variety rights, or plant breeders' rights, provide breeders with exclusive marketing rights to novel plant varieties for 20 years.

Australian law protects trade secrets. However, outside of this potential protection, the knowledge, innovations and practices of indigenous peoples (eg, the Aboriginal and Torres Strait Islander peoples) are not protected by the intellectual property system. (ANZECC, 1994)

Other International Conventions

Australia is a member of the World Trade Organization, and has ratified the Biodiversity Convention.

4.9.2 Current Ideas, Approaches and Activities

(a) Existing Legal Framework for Regulating Access to Genetic Resources⁸⁰

Regulation of sample collection for scientific research is the responsibility of nature conservation and other land management authorities in each state and territory as well as the Commonwealth Government. All governments have acted to regulate collection activities, in one way or another. Most have established a National Parks and Wildlife Service (or equivalent) authority, that issues permits for the collection of native flora and fauna in protected or Crown land (national parks, forest or fauna reserves, or other Crown lands) and in some cases, in privately-held land, as well.

In May, 1992, the Commonwealth, States and Territories adopted the *Intergovernmental Agreement on the Environment* (IGAE), which defined the roles, responsibilities and interests of all levels of government with respect to environmental matters, to ensure a cooperative national

⁸⁰ This discussion does not include marine resources. Interested readers are referred to the ANZECC Report and the CCST one, for details of the international and domestic frameworks governing access to marine resources.

approach to these issues. The Commonwealth Government has responsibility for foreign affairs and ensuring that international obligations are met -- a broad power, in view of the provisions of, eg., the Biodiversity Convention; it also has responsibility for the management of living and non-living resources on land it owns or occupies, external territories and marine areas. The States and Territories have responsibility for the policy, legislative and administrative framework within which living and non-living resources are managed within the State or Territory. (CCST, 1994, p. 34.)

The existing legislation can be briefly summarized as follows:⁸¹

(i) Western Australia

Under the *Western Conservation Act, 1950*, property in fauna is vested in the Crown until the fauna has been lawfully taken. The *Wildlife and Conservation Act (1959)* gives the Crown sovereignty over protected flora located on Crown lands. Lawful access to the genetic resources in flora and fauna is granted pursuant to licensing agreements. Protected flora on private land may be taken by the owner/occupier, or with his/her consent. However protected flora that has been declared "rare flora" may not be taken without the consent of the responsible Minister of the State.

The *Conservation and Land Management Act, 1984* (as amended, 1993), authorizes the Minister and Executive Director of the Department of Conservation and Land Management, to administer the licensing system for the taking of flora in the State. The 1993 amendment to the Act provided specifically for promotion and encouragement of the use of flora for therapeutic, scientific or horticultural purposes for the good of people in Western Australia or elsewhere, and for the undertaking of any project or operation relating to the use of flora for such a purpose. (CCST, 1994, p. 39)

(ii) Victoria

The two relevant statutes in Victoria are the *Wildlife Act, 1975*, which protects all indigenous vertebrate species (excluding fish and humans), and certain invertebrates, in both cases whether alive or dead and including skin, skeletal material, organs or any other part thereof, and eggs; and the *Flora and Fauna Guarantee Act, 1988*, which regulates "protected flora".

The taking of wildlife from the wild is generally prohibited in Victoria, except in certain stipulated circumstances. The exceptions include persons conducting bona fide research under a permit issued by the Department of Conservation and Natural Resources, and aboriginal peoples acting under a permit issued by that Department. In the latter case, the right is restricted to taking non-threatened wildlife from the wild for cultural, not commercial, purposes.

⁸¹ The following information, except where otherwise noted, is drawn from ANZECC, 1994.

Statutory and common law has held that legal access to indigenous flora of Victoria is dependent on land tenure. The Crown holds property rights to flora ("in the physical sense as opposed to genetic entities"⁸²) on Crown lands. Access is governed by the regime regulating Crown lands, with specific provision made for permits and licences for particular purposes (eg, research purposes in national parks; removing forest produce from reserved forests, etc.).

The *Flora and Fauna Guarantee Act* regulates "taking", keeping, moving and processing of "protected flora", as defined by Order of the Governor in Council. "Taking" is defined to mean killing, injuring, disturbing or collecting. Under the Act, a licence, permit or Order of the Governor in Council is required prior to "taking" protected flora from Crown land, from any land which is part of the critical habitat of the flora, or from any land (including private) for the purpose of sale. Trading, keeping, moving and processing protected flora all require similar authorization. (Quaere whether "processing" includes genetic screening and/or modification; if so, this could be used to assert control over all such use of protected flora, including after an authorized "taking", if the prospective processing was not part of the authorization.)

(iii) Queensland

The Queensland Government has expressed its desire to encourage and nurture the expansion of a pharmaceutical research and development industry in the state, with particular emphasis on the supply of natural resources for genetic screening. (ANZECC 1994, p. 15) It is already engaged in one 10-year project with a university to screen the state's estimated 9,000 plant species as well as sponges and corals.

The *Nature Conservation Act 1992* regulates access to many of the biological resources in the state. The Act provides that the State of Queensland owns property in the wildlife in a national park, conservation park or a resource reserve. All protected animals and protected plants (excluding protected plants on private land) are similarly the property of the State, subject to that property passing to another under the Act. The Act is presently silent on the question of ownership of, access to and use of the genetic material of indigenous wildlife of the State.

The Queensland Government decided to pass legislation vesting ownership of the genetic material of Queensland wildlife in the State; regulating access through a permit system to that genetic material; and authorizing the State to conclude financial agreements regarding the use of genetic materials. As of March, 1994, the legislation was still being drafted, and consultation with the various interested parties was still on-going.

The Queensland Government has also reportedly been considering amendments to the *Nature Conservation Act* that would ensure that if indigenous plants or animals yielded innovations

⁸² ANZECC, 1994, p. 14.

beneficial for human use, royalties from any such innovations would be shared by the State. (CCST, 1994, p 39)

(iv) Northern Territory

There is no specific legislation dealing with access to genetic resources in the Northern Territory. The *Territory Parks and Wildlife Conservation Act* regulates the taking and/or commercial use of certain plants, animals and parts of animals. All indigenous plants on Crown land and leasehold land are the property of the Territory under the Act, and any commercial use is subject to licence. More stringent control is exercised with respect to certain stipulated protected flora. There is no provision for Territory ownership of plant derivatives.

Collection of flora and fauna for scientific purposes is subject to licensing, which requires disclosure of details of the disposal of any specimens taken.

(v) The Commonwealth of Australia

Commonwealth legislation regulates the export of a large variety of living organisms, and specimens derived therefrom. See: the *Wildlife Protection (Regulation of Exports and Imports) Act 1982*, and the *Customs (Prohibited Exports) Regulations*. However many categories of genetic resources are currently not subject to export controls, including in particular seeds, fruit and other material derived from native plants. (ANZECC, 1994; CCST, 1994)

In conclusion, the Australian reports have concluded, "There are presently no adequate mechanisms to control access to Australia's genetic resources and to enable Australia to obtain a fair and equitable share of any benefits arising from providing such access." (ANZECC, 1994, p. 17; see also CSST, 1994, p. 34)

(b) The 1993 ANZECC Task Force (ANZECC, 1993)

In accordance with the IGAE of 1992, the Australia and New Zealand Environment and Conservation Council (ANZECC) established a Task Force on Biological Diversity to report on the implications and manner of implementation of the Biodiversity Convention. The Task Force Report (the Draft National Strategy for the Conservation of Australia's Biodiversity) concluded that under existing legislation and guidelines, it was possible to export a large range and volume of genetic resources for use in overseas research and development, without appropriate returns to Australia.

The Draft Strategy proposed the following actions to remedy this situation:

- establish a Commonwealth/State Working Group to investigate and report on matters relating to access to Australian genetic resources, including the strengthening of

existing controls and legislation. [This Working Group was set up, and reported. See: CCST, 1994.]

- establish a Commonwealth/State Working Group to investigate and report on matters relating to access to Australian genetic resources, including the strengthening of existing controls and legislation. [This Working Group was set up, and reported. See: CCST, 1994.]
- through effective controls, legislation and incentives (including secure property rights), ensure that Australia participates in research into and development of, and shares the benefits from, any commercial opportunities, including the development of technologies based on genetic resources collected from Australia;
- ensure that collection of genetic resources for research and development purposes does not adversely affect the viability or conservation status of the species or population being collected or of any component of its habitat;
- encourage and support the establishment of screening programs within Australia to identify genetic products of social and economic benefit;
- ensure that Australia benefits from access to and use of its genetic resources through existing arrangements such as plant variety rights and patent legislation, and any new arrangements that are developed;
- encourage and support the development and use of collaborative agreements safeguarding the use of traditional knowledge of biological diversity, taking into account existing intellectual property rights;
- establish a royalty payments system from commercial development of products resulting, at least in part, from the use of traditional knowledge;
- establish or strengthen networks of culture collections of microbial species, including those of medicinal, agricultural and industrial importance; and
- encourage germplasm banks to identify and develop commercial and other applications of germplasm relevant to the conservation of biological diversity, especially those involving the use of plants for rehabilitation.

(c) The ANZECC, 1994 Report

In March, 1994, following up on the 1993 report, a number of ANZECC agencies prepared an issues paper, setting out information and factors which they considered should be taken into account in addressing the issue of access to Australia's genetic resources. The paper deliberately

omitted to make recommendations. The following are the key factors that the Report highlighted for consideration:

1. The control of access is an issue of national importance.
2. There is a need to agree on a suitable definition of "genetic resources."
[The Report noted that a number of different definitions are used in various contexts. To cover the full range, it defined the term to mean "materials of plant, animal or microbial origin with actual or potential use to humanity."]
3. There is increasing pressure from overseas and domestic interests to gain access to Australia's genetic resources for commercial and scientific research activities.
4. Existing mechanisms are not adequate for controlling access to the full range of Australia's genetic resources and to enable appropriate benefits to be gained from such access.
5. A number of countries are already taking action to control access to their genetic resources and obtain benefits therefrom.
6. There is a need to ensure that if access to genetic resources is granted, access is permitted in ways which avoid or minimize environmental impacts.
7. Providing access to genetic resources has the potential to provide significant commercial and other benefits.
8. Control of access should provide for capturing the full range of potential benefits, including conservation benefits, with appropriate returns to custodians of the resources.
9. Australia is a net importer of genetic resources for agriculture and forestry improvement, and work undertaken to strengthen existing access provisions should take into account the need for continuation of supplies of exotic genetic material.
10. Consideration needs to be given to facilitating and encouraging both commercial and scientific research on genetic resources and the establishment of value-added Australian ventures involved in the collection, processing, screening and development of those resources.
11. Genetic resources of potential value to overseas interests may have a wide distribution in Australia and be found within more than one State or Territory.

12. Approaches to control of access vary between States and territories, particularly in terms of the extent of coverage of flora and fauna and application of controls to genetic resources on private land.
13. Account will need to be taken of the extent of sovereign rights in the various maritime zones.
14. To be effective, any approach to controlling access to genetic resources must cover the activities of the full range of collectors and users involved with genetic resource access.
15. A cooperative and consistent approach by Commonwealth, State and Territory Governments is required to properly control access to Australia's genetic resources and to secure benefits for the Australian community.
16. In developing an approach to access to genetic resources there is a need to address: the use and ownership of the traditional knowledge, innovations and practices of Aboriginal and Torres Strait Islander peoples; benefit sharing mechanisms where individuals, group and communities may be involved; the ownership of flora and fauna on Aboriginal lands and the use of appropriate intellectual property mechanisms.
17. Consideration needs to be given to the potential loss of returns through the transfer of research results and data, eg DNA sequences, gene maps, and chemical structures, to overseas interests.
18. The Biodiversity Convention is a key international instrument which sets out certain rights and obligations regarding access to genetic resources, including the need for "prior informed consent" and "mutually agreed terms" in granting access.
19. Both *in situ* and *ex situ* sources of genetic resources need to be covered.
20. Consideration needs to be given to the establishment of a coordinated information system for recording relevant information concerning access.
21. Relevant community sectors need to be informed about the issues regarding access through awareness-raising activities.
22. Any regulatory framework requires a national approach and may involve the development of consistent Commonwealth, State and Territory legislation; guidelines covering collection and use of material, including access conditions; and the use of collaborative research agreements. (ANZECC, 1994)

(d) The CCST, 1994 Report

Also following upon the 1993 Task Force Report (ANZECC, 1993, discussed above under (b)), in February 1993 the Coordination Committee on Science and Technology (CCST) established a Working Party to examine the issue of access to Australia's biological resources. It was asked to examine what action, if any, is required to ensure that Australia's scientific, commercial and nature conservation interests are protected; Australia's national and international obligations are honoured; and a fair and equitable share in benefits is obtained by Australia. The Working Party, made up of departments and agencies, issued its report in March 1994. (CCST, 1994)

The report noted: "The key to success will be to ensure that the terms of access do not impede the global trade in and development of genetic resources, while at the same time allowing biologically diverse countries to derive greater benefit from the exploitation of their genetic resources." (CCST, 1994, p. 10)

Australia's dual interests, as both a supplier and user of genetic resources, provide an unusual perspective on the issues. Australia's heavy reliance on imported genetic materials for agriculture and forestry improvement have given rise to several initiatives, to safeguard those interests:

- the establishment of a national network of genetic resource centres aimed at conserving a basic set of germplasm of the crops of greatest strategic and economic importance to Australia, and closely integrating the Australian network with an international one proposed by the FAO;⁸³
- cooperation with other countries on the exchange of, and research into, plant and animal genetic material in mutually beneficial terms. This will be achieved by:
- continuing to support the aims, principles, procedures and codes of conduct of the FAO Undertaking, to which Australia is a party, and the International Board for Plant Genetic Resources (IBPGR), to which Australia is a donor;
- making freely available exotic germplasm held in Australian genebanks to all *bona fide* international researchers upon mutually agreed terms;
- adherence to conventions, treaties and agreements to which Australia is a party. Australia's indigenous plant genetic resources should be readily available on agreed terms, for plant breeding and other scientific purposes of human benefit;'

⁸³ It is interesting to note that Australian adherence to a revised Undertaking is likely to be combined with a bilateral agreement between Australia and the FAO, specifying that ownership of the resources in Australian-based collections of plant genetic resources would remain vested in Australia. (ANZECC, 1994, ¶ 21.)

- continuing the development and maintenance of close contacts with international and national organizations to improve the collections and exchange of germplasm and information; and
- actively seeking bilateral agreements with other countries to further the collection, conservation, documentation, evaluation and use of plant genetic resources for mutual benefit; and the free and open exchange of plant germplasm. (CCST, 1994, p. 8-9)

The Working Group recommended that a national approach to the question of access to Australia's biological resources is required. Coordinated action by the different levels of government is required in three areas:

- clarification and definition of key principles and practices to be applied in the development of regulatory regimes and in negotiations on access;
- refinement of existing regulatory regimes governing access, collection arrangements and export control of Australian biological resources; and
- development of resource valuation mechanisms, including royalty and fee arrangements.

The emphasis placed in the Biodiversity Convention on "mutually agreed terms" presents an opportunity for Australia to play a lead role in shaping international practice. The report concluded that the interests of Australia and other biodiverse countries may be protected by the adoption of the following three basic principles:

- that Australia will control access to indigenous biological resources in accordance with the provisions of the Biodiversity Convention;
- that international access to Australia's indigenous genetic resources may be granted on the basis that contracting parties recognize Australia's rights:
 - of ownership in the genetic material collected;
 - to involvement in research on biological material of Australian origin; and
 - to fair and equitable returns on, and proportionate ownership of, commercial products developed from Australian biological resources; and
- that the Commonwealth and the State Governments reserve the right to set fees/royalties or other charges relating to the granting of access to Australia's genetic resources and to receive all data, materials and reports of research relating to the commercial potential of those resources. (CCST, 1994, p. 54-55.)

The Working Group noted that intellectual property generated through scientific research and development activities, after the raw material has been collected, is "reasonably well covered by normal commercial and legal instruments." (p. 52) However issues of apportioning the returns to the government, researchers and commercial developers from the final market sales, as well as between-country transfers, are not yet clear. The report notes that there are potentially many steps in the development chain, and a state/nation and the research institutes may consider policies to set royalties or fees at one or more steps in the process. Governments will have to set policies both to determine their own shares and as guidelines for research institutes.

Actual price-setting is a separate issue yet again. The report notes international discussion of establishing new institutions to assist in valuation, but cautions that arrangements suitable for one country may not work for another. Price-setting should also differentiate between commercial and research organizations, notwithstanding that the line between them may be blurred: ultimately, all research may be applied for commercial benefit. Moreover, pricing is only one element of an effective control regime. "In reality, pricing cannot hope to reflect the true value of a resource, rather it defines an overall acceptability for all players." (p. 53)

Finally, the Working Group recommended adoption of the approaches suggested in the Draft National Strategy for the Conservation of Australia's Biological Diversity [section (b), above], in particular the following:

- Controls and regulation should ensure that Australia participates in research and development, and shares in the benefits from any commercial opportunities, including the development of biotechnologies based on genetic resources collected from Australia;
- Ensure that collection of genetic resources for research and development purposes does not adversely affect the conservation status of the species being collected;
- Encourage and support the establishment of screening programs within Australia to identify genetic products of social and economic benefit;
- Establish property rights that relate to the development and sale of genetic products and establish intellectual property rights derived from knowledge of genetic diversity, particularly regarding Aboriginal and Torres Strait Islander peoples. (p. 54-55)

(e) Other Developments

As recommended, Australia is currently considering using the Commonwealth-State consultative process to arrive at a national approach for managing access to Australian genetic resources. This process is not expected to be completed before early 1996. (Holesgrove, 1995)

In the meantime, the Department of Environment, Sport and Territories (DEST) has sponsored a research project "to produce a state-of-the-art overview and guidelines for the use of incentive instruments and mechanisms to: promote the conservation of biodiversity; encourage the ecologically sustainable use of components of biodiversity; and encourage the ecologically sustainable use of natural resources which are biodiverse."⁸⁴ The final report, which will be written for international as well as national audiences, is scheduled for completion in August, 1995.

According to the workplan, the project (which began in July, 1994) will survey Australian experiences with various incentive instruments, to identify where these instruments have been used, and to what effect. It will identify perceived barriers to use of incentive instruments as regulatory tools, and monitor new techniques and developments as they emerge. The study will include workshops, case studies, as well as extensive consultation with government, NGO, industry, rural and urban communities, and indigenous and local communities.

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⁸⁴ The Project Work Plan is available on the Internet, at: http://kaos.erin.gov.au/life/general_info/biodiv_gen.html.

4.10 New Zealand⁸⁵

4.10.1 Access to and Use of Genetic Resources

The issue of the role of intellectual property rights in establishing terms of access to or use of genetic resources in New Zealand is still in the early stages of discussion. The Department of Conservation, which controls access for scientific purposes to the lands that it administers -- roughly one-third of New Zealand's land area, and containing much of the remaining indigenous biodiversity -- recently placed a moratorium on the issuance of permits to collect genetic material for commercial purposes. The Department is currently in the process of identifying stakeholders on the issue. It is expected that it will be some time before either a new policy or legislation on bioprospecting is enacted. (Goddard, 1995)

4.10.2 Protection of Indigenous Knowledge, Innovations and Practices

One of the issues addressed in the Biodiversity Convention is the protection of indigenous peoples' knowledge, innovations and practices.⁸⁶ As demonstrated above, a number of countries and regional groups have been and are considering how to ensure that indigenous peoples' contributions to biodiversity conservation, and knowledge of applications and uses of genetic resources, can best be recognized and compensated.

The New Zealand Government and the Māori have been grappling with these questions for a number of years, both in policy discussions and litigation. Te Puni Kōkiri, the Ministry of Māori Development, has initiated a research program into the nature of Māori intellectual property and the threats to its integrity due to its indeterminate legislative status. It has also been examining mechanisms for utilising the full commercial potential of Māori intellectual property in order to raise levels of economic development, and encourage innovation. Recognizing the complexities of the task, the first stage is to delineate the theoretical underpinning for developing protective mechanisms for Māori traditional knowledge.

In 1993, an international meeting was held in New Zealand on the cultural and intellectual property of indigenous people, attended by New Zealand government representatives as well as by Māori. The decisions reached were formulated into a document known as the Mataatua Declaration on Cultural and Intellectual Property of Indigenous Peoples ("the Mataatua Declaration").

⁸⁵ Because much of the discussion of recent developments focuses on the proposals for reform of New Zealand's intellectual property laws, the usual format adopted above for the country reviews has not been followed here. In general: New Zealand is a member of the Paris Convention, UPOV 1978 (it has also signed UPOV 1991), the World Trade Organization, and it has ratified the Biodiversity Convention.

⁸⁶ This issue is considered in greater depth in the companion literature review, to which interested readers are referred.

The central themes of the Mataatua Declaration were the following:

- Indigenous peoples are the guardians of their customary knowledge and have the right to protect and control dissemination of that knowledge.
- Existing protection mechanisms are insufficient for the protection of the indigenous peoples' intellectual and cultural property rights.
- States should develop (in full cooperation with indigenous peoples) an additional intellectual and cultural property rights regime incorporating certain specified matters.
- Commercialisation of any traditional plants and medicines of indigenous peoples must be managed by the indigenous peoples who have inherited such knowledge.
- Indigenous peoples should define for themselves their own intellectual and cultural property.
- Indigenous peoples should develop codes of ethics to be observed by "external users" (eg, other hapu and iwi, as well as governmental and non-governmental agencies). (Ministry Consultation Paper, 1994, p. 10)

Te Puni Kōkiri is attempting, through research and consultation, to examine the characteristics of Māori genetic, cultural and intellectual properties, to resolve some of the issues surrounding the definition of what exactly constitutes traditional Māori knowledge. (Māori Draft, 1994, ¶ 9.)

At this stage, three generic threats to Māori traditional knowledge have been identified:

1. **Expropriation**, or the threat that Māori ownership and control and their traditional knowledge is alienated from them. One example discussed throughout the Māori Draft and the Ministry Consultation Paper relates to trademark protection, namely the possible registration by a third party of a mark that includes a traditional Māori symbol.
2. **Inappropriate use**, or the threat of an element of traditional Māori knowledge being used in a manner that gives offence to Māori. This could be avoided through application of the "contrary to morality" ground for rejecting a patent application; however, there is uncertainty both over the application of this ground, and over which group of individuals should determine what is "inappropriate."
3. **Overprotection** of traditional Māori knowledge could lead to the underutilisation of its productive capacity. An overly restrictive property right would deter third parties from attempting to use that knowledge for commercial purposes. Consequently Māori would lose

out financially, and without the opportunity for traditional Māori knowledge to be developed and modified, there is a risk it would become irrelevant to Māori. (Māori Draft, 1994, ¶ 11.)

The Draft indicates that *contemporary* Māori intellectual and cultural property appears to be adequately protected, but not *traditional* Māori knowledge. The main technical barrier confronted is the inability to define a collective property right. Recognizing that the concept of collective property rights represents a departure from current intellectual property rights conventions, the draft suggests several options of structures in which to vest collective genetic, intellectual and cultural property ownership rights. These include a centralised agency or commission, a decentralised iwi ownership structure, other corporate organization options (eg, private companies or trusts), or a combination of these.

The Draft notes:

Providing a monopoly property right to Māori over the productive part of tikanga Māori would allay any fears of the knowledge being alienated from Māori (as ownership status is defined) or used inappropriately (as consent would have to be sought from owners). It would also encourage appropriate commercial utilisation, as ownership rights could be assigned to third parties by owners for a royalty payment. In this fashion the assignation of property rights to traditional Māori knowledge would allow control over use and permit trading incentives. In addition it should overcome Māori fears of being locked out of the development of their own assets. (Māori Draft, 1994, ¶ 12.)

Two recent developments in particular may lead to a resolution of some of the points in contention, with potentially far-reaching implications:

(a) Treaty of Waitangi Claim (Wai 262)

Māori have brought a claim (Wai 262) against the government of New Zealand under the Treaty of Waitangi, claiming ownership of indigenous flora and fauna. The Treaty of Waitangi is the foundation document for New Zealand, signed in 1840 between Māori tribes and the British Crown. It sets out the responsibilities and obligations of each partner. Among other things, the claim states:

- the Treaty of Waitangi guarantees Māori absolute authority over indigenous flora and fauna;
- the Treaty therefore vests in iwi "all rights relating to the protection, control, conservation, management, treatment, propagation, sale, dispersal, utilisation and restrictions upon the use of indigenous flora and fauna and the genetic resources contained therein": and

- the Crown has denied Māori proprietary interests in indigenous flora and fauna, in breach of the Treaty, in a number of ways, such as:
 - allowing the patenting of inventions, and the granting of plant variety rights [plant breeders' rights] in relation to indigenous flora;
 - "permitting breeding of *hebe* in the horticultural and nursery trade in the domestic and international markets"; and
 - "permitting and encouraging extensive land clearance and habitat destruction, which has detrimentally affected the species *pohutukawa*".

(Ministry Discussion Paper, 1994, p. 9; Goddard, 1995)

The Wai 262 claim is scheduled for a pre-judicial hearing later this year.

(b) Proposed Revisions of New Zealand Intellectual Property Legislation

New Zealand intellectual property legislation is, for the most part, 40 years old, and in the view of many, in need of updating. The *Patents Act 1953* excludes the following "inventions" from patentability: mere discoveries; inventions the use of which would be contrary to law or morality; a method of medical or cosmetic treatment of the human body; and an invention which is a substance capable of being used as a food or medicine, which is a mixture of known ingredients, possessing only the aggregate of the known properties of the ingredients or is a mere mixture.⁸⁷

The *Plant Variety Rights Act 1987* protects plant varieties that are new, distinct, homogenous, and stable. A plant variety right may be obtained for varieties which are either introduced from abroad, or of indigenous New Zealand origin. A species cannot be protected by a plant variety right, only new varieties. The holder of a plant variety obtains the right to licence others to produce for sale and to sell reproductive material of the protected variety; charge a royalty on all sales of reproductive material; and sue for infringement of these rights. Except with respect to vegetatively propagated fruit and ornamental varieties, the Act preserves the farmers' privilege, allowing farmers to save harvested seed of a protected variety and resow it to produce another crop.

Two sets of amendments to the existing legislation on intellectual property rights are proposed:

The first is the "GATT Bill", designed to amend New Zealand legislation to meet the obligations set out in the TRIPs chapter of the WTO Agreement. Essentially, the GATT Bill would amend the *Patents Act* to remove most of the exclusions from patentability, except that the exclusion of inventions that are "contrary to law or morality" would be retained. As will be seen below, it is proposed to remove this exclusion under the second set of amendments; however, since

⁸⁷ "New Zealand Patent Law & Practice," by Simpson Grierson Butler White, dated October 1994, in Lester Nelson, ed., *Digest of Intellectual Property Laws of the World*.

it is permitted under TRIPs, the Ministry decided to leave it in for the time being, to enable further consideration of the issue of exclusions, in particular given the concerns of Māori and others.

The Ministry notes that, "In some countries, exclusions relating to inventions that are contrary to morality have been used to prevent the patenting of inventions relating to human life. The exclusion has not been used that way to date in New Zealand." (Ministry Discussion Paper, p. 15)

The second set of amendments, more extensive in scope, is the proposed Intellectual Property Reform Bill. In particular, the draft would repeal all exclusions from patentability, including that relating to inventions that are contrary to law or morality. The reason is that the Ministry considers it is not appropriate for the Commissioner of Patents to determine what is and is not "moral." It is believed that the preferable way to control "socially undesirable" inventions is by way of legislation to control the use and development of such inventions, not by patent legislation. (Ministry Discussion Paper, p. 16-17)

Māori concerns in relation to patents include the following:

- the *Patents Act* does not specifically preclude the patenting of genetically manipulated native plants and animals;
- the patenting of inventions relating to human life forms (eg, DNA) is not specifically precluded;
- Māori may not be able to patent certain of their inventions because the inventions are not novel, that is there has been prior publication (ie, prior written publication) or prior public use (ie, use sufficient to enable someone else to work the invention) of the invention;
- individuals may obtain information about traditional remedies from iwi. They may then either isolate the active ingredient of the remedy and patent that, or alternatively, patent the remedy itself; and
- if an iwi were to patent one of its traditional remedies, or the active ingredient of that remedy, it would be forced to disclose details of the remedy, and the remedy would be available for public use upon the expiry of the patent. (Ministry Discussion Paper, p. 16)

Some of these concerns will be addressed in the litigation of Claim No. Wai 262; the rest are scheduled for discussion among the interested parties.

The Intellectual Property Law Reform Bill would also revise the *Plant Variety Rights Act 1987*, in particular to correct deficiencies in the Act that are hampering the effectiveness of the legislation, and to bring the law into conformity with UPOV 1991, enabling New Zealand to accede to that revision of the Convention.

The amendments would revise the definition of "owner", to mean "a person who bred, or discovered and developed, that variety, and includes a successor of that person." This would clarify that in the case of someone discovering a novel plant, the discoverer must have some input into development in order to qualify for a plant variety right.

Several other terms and definitions would be revised to conform to UPOV 1991. A definition of "essentially derived" would be added, to incorporate that principle from UPOV 1991.

The only exceptions to the rights granted the breeder under the proposed amendments, would be under section 18, which would allow any person to:

- (a) propagate, grow or use a protected variety, for private and non-commercial purposes; or
- (b) if the production of the hybrid or new variety concerned does not require repeated use of that variety, hybridise, or produce a new variety from a protected variety.

The Ministry Discussion Paper notes that the amendments would eliminate the farmers' privilege. While Article 15 of UPOV 1991 permits member States, as an option, to restrict breeders' rights to permit farmers to use the protected variety for propagating purposes on their own holdings, the proposed amendments would not do so. The Ministry Discussion Paper states:

It is proposed that New Zealand should not include in the revised Act this optional exception. The PVR Act 1987 removed the equivalent of the farmers' privilege with respect to vegetatively propagated fruit and ornamental varieties. There seems little justification why agricultural and vegetable breeders should not have equivalent rights to those enjoyed by their counterparts in the fruit and ornamental sectors. (Ministry Discussion Paper, 1994, p. 46)

In the Paper, the Ministry notes that one of the key questions asked by Māori about the existing intellectual property rights system, is whether the *Plant Variety Rights Act* can be used to prevent Māori using native plants in traditional ways. The response provided in the paper is that since the Act only relates to the use of new varieties, these rights would not be affected. (Ministry Discussion Draft, 1994, p. 10) It is possible that any anticipated impact -- for example, from the elimination of the farmers' privilege -- would be raised and discussed in the planned consultation process on the bill, noted above.

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4.11 Regional Roundtables

The International Academy of the Environment (Geneva), under the direction of Professor William Lesser of Cornell University, organized a series of roundtable discussions in 1994, to bring together eminent individuals from government, the private sector, non-governmental organizations, indigenous peoples' groups, regional and international organizations, and academic institutions, to discuss issues relating to regional cooperation for the assessment, conservation and sustainable use of genetic resources. Each roundtable focused on a particular geographic region: the first, in April, was a Latin American and Caribbean roundtable; the second, in September, an African one; and the third, in October, an Asian one.

The broad spectrum of views and perspectives represented at these roundtables made for papers and discussions that provide useful insight into current ideas under consideration in the countries and regions, and makes the results of particular note for this survey of regional and national ideas.

4.11.1 Latin American and Caribbean Round Table, 1994: Developing a Facilitating Mechanism for the Equitable and Sustainable Use of Biodiversity: Achieving National Objectives through Regional Collaboration

In April, 1994, the International Academy of the Environment sponsored a round table discussion on Latin American and Caribbean approaches to sustainable use of biodiversity, held in Mexico. Participants were invited from the Bahamas, Brazil, Chile, Colombia, Costa Rica, Cuba, Mexico and Surinam, and included individuals from government, the private sector, non-governmental organizations, indigenous peoples' groups, regional and international organizations, and academic institutions.

The participants identified the following priority requirements for regional collaboration:

- there is a need for an open, clear system of coordination of activities, at the national, regional and international levels. (The last can be accomplished through the mechanisms of the Biodiversity Convention.) This would focus activities and efforts both internally, and externally (and provide third parties with "one stop shopping").
- new and innovative approaches to financing should be made available to the business and academic sectors, to encourage local and regional businesses to take risks and initiate challenging projects.
- a database of common information, accessible to all communities and all levels (including the popular media), should be established to facilitate information exchange and increase public awareness of the importance of biodiversity and

biotechnology. In addition, individual, decentralized databases should be developed for the compilation of complete inventories.

- Maintaining the nexus between biodiversity and biotechnology assists both, and fosters exchanges of knowledge and expertise between biotechnology companies and biodiversity research organizations. This can be used to further North-South technology transfers, as well as build South-South cooperation. To achieve this, Latin American and Caribbean personnel should be sent for training to sophisticated laboratories of biotechnology companies and research organizations. In addition, emphasis should be placed on agri-biotechnology, which may offer unique opportunities for cooperation between a developing and industrialized country (and for furthering biodiversity conservation).
- Strengthening institutional capacity was considered to be extremely important. Three aspects were identified: training of individuals on the scientific, technical, policy, legal, economic and political aspects of the issues; building of relevant institutions within each country; and development of a national policy or strategy on biodiversity.
- Equitable and effective transfer of technology -- including the movement of biological resources and local information, as well as movement of expertise and equipment -- is one of the major mechanisms by which biodiversity resources can be conserved, managed, and used sustainably. Equity demands that developing countries receive benefits and compensation for the use of their resources; these benefits will be increased insofar as the developing countries provide more than physical resources. This requires preferential access to the relevant technologies.

In view of the identified needs and goals, and the facilities available, the participants developed an agenda of options of new ways to further the equitable and sustainable use of biodiversity. This included analyzing the legal framework in the particular country, both with respect to intellectual property protection and with respect to access to genetic resources. Education on the legal framework is important, in comprehensible terms made accessible to the appropriate individuals. This would include collecting and reviewing innovative and related case studies of legal frameworks.

Evaluating indigenous and local peoples' rights is required, both to enhance the awareness of rights in biodiversity and the means to embody those rights among indigenous and rural societies, and to enhance the appreciation of indigenous and local knowledge with respect to biodiversity conservation and use. Conferences, papers and case studies were proposed as means of working toward these goals.

Recognizing the weakness of current intellectual property regimes for protecting the kinds of materials likely to be generated by indigenous and local peoples in developing countries, the participants recommended instead investigating alternatives to existing legal structures, and investigating the issue of potential overlapping and conflicting rights caused by the "rights" obtained with limited description of the potential materials by, eg, several farmers or developers of a unique crop, or several groups with the same plant and know-how.

The group discussed several alternative ways to approach negotiation of access agreements between individual countries, companies and other entities:⁸⁸

- (i) leave the negotiations to the parties, that is the individual nations and the private sector groups or organizations;
- (ii) establish a negotiating group within the structure of the Biodiversity Convention, as a mandate to the Scientific Technical and Advisory Committee (STAC) or other instrument;
- (iii) establish a negotiating group within the structure of an existing institution, eg. UNIDO (United Nations Industrial Development Organization);
- (iv) establish an academic network that would provide information about different aspects of negotiations and training, as well as negotiators, lawyers, and regional scientific capacity.

Of the four alternatives, several participants indicated that the ideal would be to establish this negotiating capacity within the framework of the Biodiversity Convention.

The group concluded that there is a need for broker services in terms of information and technology transfer. It was decided this should be explored further in further round tables with participants from other parts of the world.

⁸⁸ This is the issue of a "Facilitator", proposed and elaborated by William Lesser and Anatole Krattiger. This is discussed briefly below, in the context of the African Roundtable, and considered in greater detail in the companion literature review.

4.11.2 African Round Table, 1994: Coordinated Arrangements for the Conservation and Sustainable Use of Genetic Resources, Material and Technology Transfer, and Benefit Sharing

In September, 1994, an African Round Table was held in Nairobi. It brought together leading experts from Kenya, Ghana, Egypt, Zimbabwe, Madagascar, Ethiopia, Mauritius, Malawi and South Africa, along with those from Sweden, Switzerland, Cuba, England and the United States. The participants were variously drawn from government departments and agencies, NGOs, the private sector, and bilateral and multilateral agencies. (African Round Table, 1994.)

A paper presented by Dr. Calestous Juma (then of the African Centre for Technology Studies, and recently appointed Executive Secretary for the Convention on Biological Diversity) noted, among other things, that "regulated access to genetic resources forms a key aspect of the [Biodiversity] Convention". However, the principle of "prior informed consent" has been applied only in very few cases of genetic material transfer agreements, since most agreements have failed adequately to inform about the potential value of the genetic resource. Moreover, successful technology transfer is predicated on the recipient possessing a minimum capacity level. Therefore, there is a need to effectively implement Articles 12, 17 and 18 of the Convention (information exchange, and technical and scientific cooperation), to prepare the way for successful technology transfer.

Dr Juma noted the need for guidelines on genetic material transfer agreements or a code of conduct ensuring the rights of indigenous people and local communities. He also proposed restricting access to genetic resources until country capacity is sufficient for appropriate agreements subject to prior informed consent to be made.⁸⁹ However, there is an urgent need to incorporate technology transfer in genetic material transfer projects, and awaiting guidelines would slow the capacity-building process. The participants strongly endorsed development of a national, as well as an African, strategy to strengthen the capacity for sustainable use of biodiversity.

A paper presented by Darrell Posey of Oxford University and Christine Kabuye of the EA Herbarium, National Museums of Kenya, emphasized that local community empowerment is critical for sustained development and effective biodiversity conservation. "National and international legislative policy measures to protect intellectual property should also include indigenous and traditional technologies. This would reinforce the respect for traditional knowledge and traditional resource rights regimes and ensure benefit sharing." Partnerships between local communities and indigenous people on the one hand, and governmental and NGO institutions on the other, could support community conservation efforts and resource management capabilities. "[C]ommunity controlled, local clearing houses could be created to oversee the process." Successful

⁸⁹ A Canadian official noted in discussions with this consultant that he heard this was adopted as policy by AMCEN. Attempts to verify or contradict this have not been successful to date, but queries are still outstanding.

implementation of the Convention was said to depend on the development of mechanisms, legislative and non-legislative, to involve local communities in all levels of decision-making.

A third paper, by Steven Njuguna of IUCN, Kenya, and Caroline Martinet of IUCN, Switzerland, noted the insufficiency of the existing scientific knowledge base for genetic diversity management and enhancement in Africa. Broad inventory and collection programmes, investment in database management, standardized criteria for the inventory programmes, are all needed. Information networks as part of the research infrastructure are critical to the technological development process. A wide range of assessment methods should be used to determine the total value of biodiversity resources.

Finally, William Lesser and Anatole Krattiger presented a paper proposing the concept of the Facilitator -- or a special type of "clearing house" mechanism -- in recognition of the need to provide "a centre and focus for a regionalised broker, for training assistance and for information exchange on a voluntary basis." Among other things, a facilitator could provide evaluation advice on, and facilitate harmonization of, relevant legislation and policies to ensure protection for providers and recipients of biodiversity-derived products; develop effective linkages among such providers and recipients; conduct activities to facilitate an understanding of the commercialization process for such products in harmony with, and to reinforce, the sustainable use of biological resources, to name a few.

Five topics emerged from the subsequent discussions as being of high interest to African countries:

- (1) bioprospecting;
- (2) capacity-building/ institutional building;
- (3) training;
- (4) biotechnology implementation; and
- (5) biodiversity conservation.

In order to both maximize economic utility and ensure the equitable distribution of benefits, African nations would require a comprehensive biodiversity inventory; bioprospecting capabilities; a defined commercialization strategy (i.e., specializing in chemicals, medicinal products, or food products, and ways and means to achieve these goals); political/national encouragement to launch new businesses and new products based on biodiversity; and an industrial strategy for diversification away from traditional commodities.

This suggested that **international mechanisms** be established to provide the following support in an African context:

- access to a facilitation, brokerage and business advisory service;
- a capacity building fund to support efforts to build local inventory and prospecting capacity to the point where it can deal with the private sector (financial and technical assistance);

- institutional support to launch new businesses and products; and
- support for biodiversity-based industrial strategies and policies.

The group also identified four guidelines to ensure the development of rights of indigenous people:

- full informed disclosure of commercial objectives and what will be done with the sample and information;
- respect for indigenous values, concepts of intellectual property, and limits they may place on transfer of information on exploitation of samples (eg, sacred plants or information guarded in tribe or family);
- equitable compensation appropriate to the situation (not necessarily cash), including prompt sharing of successes; and
- full discussion of risks of failure and likely consequence of success (eg, who gets compensation, and what will be the impact on the tribe.)

Training, including business and negotiation skills training, would be required for indigenous people, analogous to that required by developing country-based laboratories.

The discussants noted that biotechnology can and should aid the sustainable use of biodiversity resources, eg by genetic manipulation for increased pest resistance of crops, development of new diagnostic methods, understanding ecosystems, habitat restoration through tissue culture and rapid multiplication techniques, crop management through soil conservation, efficient breeding methods and the development of new drugs and vaccines.

It was recognized that important decisions on biodiversity conservation are made at the local level, so that local community training and capacity building are a necessary prerequisite to local biodiversity preservation projects.

4.11.3 Asian Round Table: Assessment, Conservation and the Sustainable Use of Genetic Resources: Achieving National Objectives through Regional Collaboration

In October, 1994, an Asian Round Table on the conservation and use of genetic resources was held in Indonesia. Like the earlier ones on Latin America and Africa, this brought together leading experts from government, NGOs, the private sector, and bilateral and multilateral agencies. Invited nationals were from Australia, Bangladesh, India, Indonesia, Japan, Malaysia, Singapore, Sri Lanka, Thailand, Papua New Guinea, Peoples Republic of China, and the Philippines. Some of the issues discussed and conclusions reached are set out below:

Papers presented dealt with threats to the marine ecosystem, over harvesting of certain medicinal plants (eg in China), and the need to ensure sustainable use of such resources; the Thai experience using traditional knowledge and biodiversity resources in developing new pharmaceutical products, and the importance of finding ways to share putative benefits with countries of origin and/or local communities (eg, plantation set-ups in country of origin); a comprehensive programme of the Asian Development Bank and the Government of Indonesia underway in Indonesia to strengthen the management of Indonesia's extensive system of over 350 conservation areas; and possibilities and problems in the use of the microbial strain data network (MSDN), a collection of microbial databases, which is being used less than anticipated. As with the other Round Tables, a presentation was made on the concept of a "Facilitator" or a special type of "clearing house" mechanism, that would recognize the need for a centre and focus for a regionalised broker, for training assistance and for information exchange on a voluntary basis.

There was also discussion of an interesting new project in Singapore, with the Centre for Natural Products Research, recently established at the University of Singapore through funding from Glaxo Research Plc. and the Singapore Economic Development Board. The Centre will carry out advanced screening of material derived from plants, marine organisms and micro-organisms acquired from organisations throughout the region that are authorized to obtain such materials (eg, botanical gardens). The material will be screened for active molecules that could lead to new drug development.

Of particular interest is the fact that this is yet another arrangement apparently modelled on the Merck/NCI precedents: if a commercial product is found, Glaxo has the first option to file for patent protection. The supplier of the source will receive financial compensation, particularly in the form of royalty payments.

A paper was also presented on GRIT (Genetic Resource Indexing Technologies), which is intended to enable developing countries and rural communities to perform assessments of their own genetic resources and thereby assist in the sustainable use of biodiversity. The GRIT consortium "aims for the development of novel molecular technology for the rapid and low cost DNA based analysis of diverse germplasm for users in resource-poor settings...[to be] done collaboratively with, among others, scientific equipment companies."

The discussions identified a number of options and approaches to address the problems noted. Of particular interest for present purposes are the following:

(a) National and Regional Institutional Strategies for Biodiversity Conservation

- there is a need to have a common regional policy or measures to strengthen the sustainable use of genetic resources, especially with respect to bioprospecting; since this would require formal arrangement with other countries, established diplomatic channels and protocols will have to be observed; this does not preclude each country setting its own policy and developing regulatory measures to ensure bioprospecting is ecologically sustainable as well

as socially and ethically acceptable; the possible implication of the harmonisation of regional policy and measures includes the common sharing of benefits as well as risks; there is also the need to encourage the private sector and government sectors to become partners in integrating development with conservation

- creation of a regional clearing-house mechanism to facilitate regional approaches may be considered subject to mutually agreed terms and conditions by all member countries in the region; institutional linkage through collaboration, harmonisation and complementation of projects and programmes within the region will strengthen transfer and exchange of technology
- there is a need for an integrated approach to *in situ* conservation, particularly with respect to protected areas; such an approach should consider the social, economic, cultural and scientific aspects of conservation; protected areas should be managed so as to ensure stakeholders, in particular the tribal communities, can derive benefits from their conservation effort; institutional and human capacities need to be developed through integrated training at the regional level (eg, applying the Integrated Protected Areas System of the Philippines and the Biosphere Reserve Concept⁹⁰)
- establish an expanded network of integrated protected area systems in the region, to be used as bases for collaborative training and monitoring; biotechnology should be used, but linked with on-site programs, as part of a large-scale co-ordinated effort to improve propagation and conservation of threatened indigenous species; need to expand and co-ordinate monitoring and evaluation capabilities (eg, biodiversity status)
- there is a need to have access to information such as by electronic networking
- public awareness of the value of biodiversity conservation and how to sustainably use genetic and biological resources must be heightened through programmes, campaigns

It was noted that trade in genetic resources requires assistance in negotiation, monitoring of violation/accountabilities and legal assistance, as well as information on equity in trade arrangements. Components of these could be fulfilled by existing institutions (eg, Asia Pacific Economic Cooperation, regional legal networks, IUCN). A clearing house could identify needs and potential partner institutions.

⁹⁰ The Integrated Protected Areas System (IPAS) in the Philippines is an extensive, detailed program of protected areas management, with biodiversity conservation and sustainable development as primary goals. (Discussed in detail in Catibog-Sinha, 1994)

(b) Conservation and Sustainable Use of Biodiversity by Local Communities and Indigenous Peoples

The importance of the role of local communities in using and improving biodiversity resources -- including genetic resources used for agriculture, medicinal purposes, or otherwise affecting the environmental status of the area -- was stressed. Bioprospecting is a minor aspect of genetic resource use and conservation, as compared with the actual use and improvement of the resources in and by the local communities. Empowerment of the local community was emphasized as a key aspect of biodiversity conservation. Strategies to develop community benefits from bioprospecting need to be developed, recognizing the intrinsic, functional, cultural and economic value of the biodiversity. However the emphasis placed in the discussion was on providing opportunities for the indigenous communities to participate, understand and use the biodiversity; from the report of the discussion, there does not appear to have been any mention of intellectual property rights.

Several approaches were identified to increase benefits to local communities, including establishing a system of disincentives/incentives (eg, modified land tenure regimes); providing more information on the resources and their use through local and collaborative regional inventory programmes; providing local training programmes on management of genetic resources, local marketing and negotiation of deals; and providing training programmes on value-adding activities and improvements by the local communities (agricultural improvements, medicinal plant utilisation).

Consideration was also given to the benefits to small-scale farmers of the introduction of biotechnologically improved varieties. Concern was expressed that this could endanger biodiversity, and that a management programme for the improvement of local varieties was more effective.

(c) Facilitating and Clearing House Mechanism

The group considered the concept of a facilitator to facilitate fair and equitable deals between sources and users of genetic resources, and in so doing, to promote cooperation in the transfer of technology, human and information resources, and skills to the countries in the region. Increasing interest in bioprospecting would be the initial focus, but that would be understood to encompass the development of technology in source countries, appropriate to the needs and aspirations of local and indigenous communities, and appropriate to the conservation and restoration of the habitats and ecosystems in which the genetic resources are located.

The report details a list of functions for the facilitator, and alternative facilitating mechanisms to try in the region. These last ranged from an intergovernmental regional body set up by formal agreement of the countries in the region, to a private sector firm or institute, set up on either a profit or non-profit basis.

The facilitator's role would likely overlap with that of the clearing house mechanism to be established under the Biodiversity Convention. That is seen as facilitating the promotion of scientific and technical cooperation. Participants envisaged the clearing house as covering potentially "high added-value activities," including bioprospecting and *in situ* conservation activities, outside those relating to the main staple and commercial food interests covered by other arrangements.

This Round Table took place prior to Philippine Executive Order on bioprospecting. Presumably the regime established for the Philippines will present an alternative model for the region.

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5.0 SURVEY OF INTERNATIONAL ACTIVITIES⁹¹

Summary:

Activities at the international level surrounding the issues of intellectual property rights, biotechnology and biodiversity appear to be increasing in number and scope. This includes both inter-governmental organizations and non-governmental ones.

The World Trade Organization has become the critical inter-governmental organization, besides the Biodiversity Convention framework, concerned with these issues. The WTO Committee on Trade and Environment considered the relationship between the WTO and the Convention in June, 1995, and will do so again in April, 1996. The initial discussion was general in nature, reflecting the positions and views that had developed in the Convention context and the negotiations on the TRIPS Agreement. The second discussion is expected to define the central areas of concern that the WTO members believe require further consideration or study. In May, 1996, the Committee will determine whether this area is one to be brought forward to Ministers at the WTO Ministerial meeting in December, 1996.

Of primary interest is the treatment of the patenting of life forms in TRIPS, and the requirement for patent protection to be available for all technologies, without discrimination. Restrictions in TRIPS on the compulsory licensing of technologies is also an area of interest for many states. The relationship of the two agreements in the event of a dispute that might involve them both is also considered an important element, especially by environmental groups.

The World Intellectual Property Organization (WIPO) has not, to date, played a significant role in this area. This does not appear likely to change in the near future, despite their role as the "guardian" of international intellectual property agreements.

The United Nations Human Rights Commission, Working Group on Indigenous Peoples, has assumed a high profile role in this area, focussing on the issue of indigenous intellectual and cultural property. While not related expressly to the Biodiversity Convention, this Working Group has produced documents that will impact on developments in the Convention context. Most notably, they have espoused a dynamic and wide ranging view of what should be considered as the rights of indigenous peoples in this area, as well as a strong procedural position on the need to ensure the active involvement of indigenous representatives in any process that seeks to address these issues. A Draft Declaration on the Rights of Indigenous Peoples has now begun its negotiating phase under this Working Group, and includes significant references to the issues raised by the Convention.

⁹¹ This part was contributed by Howard Mann, who interviewed representatives of a number of the groups discussed here, during visits to London and Geneva. His assistance, and that of the individuals and organizations with whom he met, is gratefully acknowledged.

The OECD is seeking to develop a stronger appreciation of the responses to the Convention that its members have made, or could bring forward. A survey of members will provide the background material for an OECD meeting to be held early in 1996 in Australia. This meeting is not designed to develop a single response strategy.

The non-governmental response from environmental groups (ENGOS) has focussed on two issues, and their linking: the local conservation and sustainable use of genetic resources and the role and rights of indigenous peoples. Linking these two issues has provided both significant institutional developments and contacts among previously diverse groups, as well as a powerful rights-based approach to many issues.

Ensuring an equitable sharing of benefits for the use of genetic resources, and the necessary transfer of technologies, is seen as critical to providing the full economic value for local conservation efforts. This, in turn, will ensure they can continue to be made. Many ENGOS have reluctantly come to accept that the economic interaction necessary to do this will require some recognition of intellectual property rights over resulting new products. The approach in this regard has become, increasingly, one of providing the assistance needed to ensure that mutually agreed terms of access lead to an equitable sharing of the benefits flowing from these rights.

Finally, it is noted that business groups have not been as active in this area as in other international agreements in the form of international associations. Still, many businesses and institutions continue to show leadership in the development of bilateral agreements that implement, in different ways, the intent and objectives of the Convention in the absence of implementing legislation that requires this. In addition, several private sector codes of conduct for the harvesting of genetic resources have been developed to guide professional activity in this area.

5.1 Introduction

The issues reflected in the Biodiversity Convention are of paramount importance to the environment and humanity. This is reflected in the range of interest that continues to be directed at the Convention since the Rio Conference of June, 1992. Still, it can be acknowledged that, in international terms, the general level of interest in relation to this Convention appears to be lower than in relation to the Climate Change Convention which was also opened for signature at UNCED. This is seen both in terms of the media interest, and the ENGO and business community involvement. This does not in any way diminish the importance of the issues from an environmental or sustainable development perspective, or reduce the political divisions that lie behind the many uneasy compromises reflected in the Convention. It does, however, indicate the lower level of public attention being paid to the Convention, as well as the lower level of NGO activity. These lower levels, however, should not be confused with less intensity or belief on the part of those many groups, some 120 business and environment NGOs at the first COP, who continue to be actively engaged in the issues.

This survey of international level activities reviews inter-governmental activity at five key organizations. These are the World Trade Organization (WTO), World Intellectual Property Organization (WIPO), United Nations Human Rights Commission, Working Group on Indigenous Populations, and the OECD. The activities of the Biodiversity Convention Secretariat and Food and Agricultural Organization (FAO) have, of course, already been reviewed.

At the non-governmental level, environmental groups, indigenous peoples' groups and business groups are reviewed in a collective way: it would be impossible to review the individual activities of, for example, the over 100 NGOs that participated in the first Biodiversity Convention Conference of the Parties. However, because of the lower level of business activity, relatively more attention is paid to the environmental and indigenous groups.

5.2 Intergovernmental Organizations

5.2.1 The World Trade Organization

It has already been noted that the Uruguay Round negotiations to revise the GATT included issues of direct relevance to the Biodiversity Convention negotiations. These were centred in the negotiation of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). The primary issues were threefold: first, the general protection and respect for intellectual property rights over technological and industrial production; second, the patenting of life forms; and third, the availability of compulsory licensing as a means to limit the applicability of patents. Each of these is addressed in TRIPS, and resolved at least on a temporary basis. A related issue is the primacy of the GATT dispute resolution process over that of the Biodiversity Convention.

A full review of TRIPS is beyond the scope of this report. Some primary features in relation to the specific issues may be briefly noted, however. TRIPS establishes minimum standards for providing intellectual property protection and enforcement among participating countries. The key concept here, set out in the opening words of the preamble, is "the effective and adequate protection" of such rights. The primary means for doing this is the enactment of national laws. These laws must then be applied in an equal manner between the countries' nationals and foreign nationals that may seek a patent on similar products, and between domestically produced and imported products.

The rapid expansion of the GATT into the developing countries has meant the inclusion of many states without the technical, legal or administrative infrastructure to fully administer patent and other IPR regimes. This lack of infrastructure is all the more critical in the area of biotechnology, where specific technical demands abound. In general, this problem has been dealt with through a phase-in period for developing countries. Most developing countries are granted a five year period before the TRIPS requirements come into force for them. Least-developed countries are given up to eleven years. Other delays are provided for in the pharmaceuticals and agricultural chemical areas for technical reasons associated with the regulatory delay periods for

approval of these products.⁹² These periods provide some flexibility in terms of the timetable for implementation, but do not otherwise alter the principles or ultimate results expected.

The TRIPS patent regime would encompass all fields of technology. Thus, under TRIPS, there is no basis to exclude or discriminate against, as a category, environmentally-related technologies or biotechnologies, the two classes of technology focussed on in the Convention, from national patent laws.⁹³ (This is subject to an exception noted below.) As a result, TRIPS provides no basis for access to such technologies on a non-commercial basis. In the trade agreement context, this is to be expected, as it is taken as a principle that intellectual property rights contribute to the development and transfer, through trade, of such socially beneficial technologies.⁹⁴ Thus, much as it did in the Biodiversity Convention, the issue of access to patented technologies outside a contractually agreed context comes back to the concept of compulsory licensing. This can be associated with the debate on Art. 16(5) in the Biodiversity Convention.

Article 31 of TRIPS covers the main issues in compulsory licensing. It allows for compulsory licensing, without special justification of the grounds for doing so, as long as the procedural and compensatory steps required by the same article are taken. One such condition is that the right holder be paid adequate compensation, based on the circumstances of each case. A second is that the compulsory license itself and the remuneration offered in place of agreed access to the technology both be subject to review by judicial or other independent means. This situation may in large part explain some of the United States concern for the prospect of compulsory licensing being "authorized" by Art. 16(5) of the Convention in that it did not expressly prohibit such an act.⁹⁵ Still, it is apparent that the conditions placed on compulsory licensing are fairly restrictive and should not create a large risk.

A further area of concern has been the patenting of life forms. This issue was sidestepped in the Biodiversity Convention through, essentially, its reference to other international law. Under TRIPS, countries may exclude only certain types of life forms from patentability:

plants and animals other than microorganisms, and essentially biological processes for the production of plants or animals other than non-biological and micro-biological processes. However, Members shall provide for the protection of plant varieties either by patent or by an effective sui generis system or by a combination thereof. The provisions of this sub-paragraph shall be reviewed four years after the entry into force of the Agreement Establishing the WTO. (Art. 27.3(b))

⁹² TRIPS, Arts. 65, 66, 70.8, 70.9.

⁹³ TRIPS, Art. 27.1

⁹⁴ TRIPS, Art. 7.

⁹⁵ See the review of the Biodiversity Convention, Part 2, above.

This formulation requires two explanations. First, the ability to exclude essentially biological processes is limited to processes other than non-biological and microbiological processes. These latter two types of processes, therefore, cannot be excluded from patentability. Thus, processes of generating life forms through cell manipulation or genetic transfers are not covered by the exclusion from patentability. (Correa, 1994, p. 26)

Second, a further stipulation appears in relation to plant varieties. Here, Members are required to provide either patent (the US approach) or *sui generis* protections (the European approach). Developing countries had been initially opposed to either of these two required approaches. (Correa, 1994) The effect of this requirement, from a biodiversity negotiating perspective, is that membership in both GATT and the Biodiversity Conventions will create the obligation to provide some form of protection of plant varieties, even though this was not the specific result of the Biodiversity Convention.

The final part of para. 27.3(b) established the need for a four year review of this provision. This reflects the serious divisions in the negotiating process, and is a harbinger of the debate to come when the review takes place.

Regarding indigenous and local knowledge, there is simply nothing in TRIPS that promotes the recognition of such rights in an intellectual property sense. Indeed, the issue was not specifically addressed during the negotiations of the Agreement. Some analysts have pointed, out, however, that TRIPS is geared quite specifically to the developed country conceptions of intellectual property rights, which themselves do not readily accommodate indigenous and local knowledge. Thus, as TRIPS specifically enumerates the types of rights it covers, and the criteria attached to each type, the identification of indigenous or local intellectual rights in one form or another would not receive automatic international protection through TRIPS. (eg., Correa, 1994, pp. 33-38)

Finally, there is special concern over the broader implications of the dispute resolution processes in the event a dispute potentially involves both agreements. This concern is particularly significant as only the WTO has a binding dispute resolution process. Further, under the WTO process, only those agreements specifically within its mandate are considered for dispute resolution purposes. As a result, a disputant could not use the provisions of the Biodiversity Convention to justify conduct that might be contrary to TRIPS or other GATT law. While this is consistent with the goals of international trade liberalization, environmentalists have long raised this as a concern for the goals of environmental agreements. This environmentalist concern is increased by the legal priority under international law attributed to a subsequent convention dealing with the same subject matter as an earlier convention.

The TRIPS negotiations were essentially concluded with the draft text produced in December, 1991, prior to the conclusion of the Biodiversity negotiations. This factor did not lead, however, to the introduction of amendments to the draft text by any states in response to the results of the latter agreement.

The relationship between TRIPS and environmental issues, including the Biodiversity Convention, was considered in a general way by the WTO Committee on Trade and Environment at its June 21-22, 1995 session. The official public report on the meeting shows a range of issues being covered that is consistent with previous positions and orientations, as noted in Part 2 above.⁹⁶ It remains on the agenda for further consideration again in April, 1996. Observers have suggested that no specific action on this WTO Trade and Environment Committee item is anticipated for the WTO Ministerial meeting in December, 1996.

Notably, the Trade and Environment Committee has now emerged as the critical forum for the main decisions at the intersection of trade and environment issues. This institutional issue will be addressed in the discussion of the environmental groups, below.

5.2.2 World Intellectual Property Organization (WIPO)

WIPO has not been an active player in most of the issues related to the Biodiversity Convention. Still, its agreements are of importance. In particular, the Paris Convention provided, until TRIPS, the most widespread international agreement on international patent protection. It established the format whereby minimum standards were set down in international agreements, with which national laws would have to comply. Outside these parameters, nations could set their own standards. This approach is continued in the TRIPS Agreement, but with ever-increasing scope given to the set "minimum standards". However the extension of these intellectual property standards to the trade forum, with the attendant trade sanctions, has significantly enhanced its power. As a result, much of the focus on the IPR debate in relation to the issues raised has effectively shifted to that forum.

WIPO has produced material on the transfer of environmental technologies that might be relevant to the conservation of biodiversity, and that may be subject to patents, in particular through a Meeting of Experts on the Acquisition by Developing Countries of Environmentally Relevant Technology Protected by Intellectual Property.⁹⁷ This meeting focussed on the availability of such technologies, and provided information on identifying and accessing them, in the context of the applicability of the protections in the North-South context.

The focus on information and modalities of access remains the main thrust of WIPO's efforts in this area, without specific focus on any one international environmental agreement. In addition, WIPO has not become actively engaged in the issue of the protection or remuneration of indigenous

⁹⁶ WTO Trade and Environment Bulletin No. 4, 14 August 1995.

⁹⁷ This Meeting of Experts was held October 21 and 22 in Geneva. It was organized by the United Nations Conference on Environment and Development and WIPO, with a focus on the accessibility of, and modalities for accessing, these technologies. At least one paper, however, did question the contribution of expanded IP protections under the GATT, and its role in favouring increased industrial monopolization by the North at the expense of the South. See Arruda, 1991.

knowledge, either in the context of the Biodiversity Convention or the work in the United Nations Working Group on Indigenous Populations as it relates to the recognition, protection and rewarding of indigenous knowledge. Indeed, with the exception of the work on access to environmentally sound technologies, WIPO has adopted a low profile on the environmental issues that do not specifically fit within the major objectives for the protection of intellectual property rights.

5.2.3 UN Human Rights Commission, Working Group on Indigenous Populations

There are currently two related strands of work under the Working Group on Indigenous Populations. The first has led to a draft set of Principles and Guidelines for the Protection of the Heritage of Indigenous Peoples. The second process has produced a Draft Declaration on the Rights of Indigenous Peoples. The relevance of each of these to the present report will be discussed briefly.

The draft Principles and Guidelines for the Protection of the Heritage of Indigenous Peoples are contained in a study prepared by Mrs. Erica-Irene Daes as Special Rapporteur for the Working Group.⁹⁸ The full background to the draft Principles and Guidelines is contained in a report prepared in 1993, also by Mrs. Daes, for the Working Group. It explains the concept of indigenous heritage in broad terms:

"Heritage" is everything that belongs to the distinct identity of a people and which is theirs to share, if they wish, with other peoples. It includes all of those things which international law regards as the creative production of human thought and craftsmanship, such as songs, stories, scientific knowledge and artworks. It also includes inheritances from the past and from nature, such as human remains, the natural features of the landscape, and naturally-occurring species of plants and animals with which a people has long been connected.⁹⁹

This view of heritage is derived from the conception of indigenous peoples that all things come from the same source, the relationships between the people and their land, their kinship with the other living creatures that share the land, and with the spirit world.¹⁰⁰ Mrs. Daes' report concluded that current international law conceptions of intellectual property cannot provide the protections she envisages in her report to this definition of heritage.

⁹⁸ "Protection of the heritage of indigenous peoples", Preliminary Report, E/CN.4/Sub.2/1994/31, 8 July, 1994, Annex.

⁹⁹ "Study on the protection of the cultural and intellectual property of indigenous peoples", E/CN.4/Sub.2/1993/28, 28 July, 1993, at p. 8.

¹⁰⁰ *Ibid*, p. 7-8.

The second major background item for present purposes is the view that only the group or community that possesses the heritage can consent to its sharing. That is:

in whatever way consent is given, it is temporary and revocable: heritage can never be alienated, surrendered or sold, except for conditional use. Sharing therefore creates a relationship between the givers and receivers of knowledge. The givers and the receivers continue to recognize and repay the gift.¹⁰¹

The report also recognizes the existence of indigenous laws governing the consent process in each case. Various sections of the report then go on to review a range of issues relating to indigenous "heritage", including medical research and bio-prospecting, indigenous science and technology, community control of research,¹⁰² etc..

The Principles and Guidelines cover these issues and concepts in some detail, with 59 individual paragraphs. The most relevant Principles include:

- Principle 5: the ownership and custody of indigenous peoples' heritage is collective, inalienable and permanent.
- Principle 8: in order to control their heritage, indigenous peoples have to exercise control over all the research conducted within their territories or which uses them as subjects of study.
- Principle 9: the free and informed consent of the traditional owners of the heritage should be an essential pre-condition to their use.
- Principle 10: the indigenous people should continue to be the primary beneficiary of any commercial use of their heritage.

The most relevant guidelines include:

- Guideline 11: defines heritage to include, *inter alia*, all the knowledge or objects the nature or use of which has been passed down from generation to generation and which is regarded as pertaining to a particular peoples, clan or territory, as well as any objects or knowledge created in the future based on this heritage.

¹⁰¹ *Ibid*, p. 9.

¹⁰² The report suggests that the growing number of journals and institutes in the North devoted to the research of indigenous knowledge may constitute more of a threat to indigenous peoples than a benefit.

- Guideline 12: this heritage includes all scientific, agricultural, technical and ecological knowledge, including cultigens, medicines and the phenotypes and genotypes of flora and fauna.
- Guideline 32: the inventorying and identification by researchers of all indigenous heritage in their custody.
- Guideline 33: the return of such heritage on demand, unless a formal agreement for its shared custody or use is obtained.
- Guideline 35: the obtaining of prior informed consent by all researchers for study on any previously undescribed species of flora or fauna, including plant varieties and naturally occurring pharmaceuticals.
- Guideline 36: the obtaining of prior informed consent to the publication of such research.
- Guideline 37: an agreed immediate moratorium on the Human Genome Diversity Project, and the suspension of such research unless and until it is broadly and publicly supported by indigenous peoples.
- Guideline 38: all efforts should be made to increase access of indigenous peoples to scientific and technical education and to all forms of research which may affect or benefit them.
- Guideline 40: business and industry should respect the same guidelines as researchers (i.e., 32-39).
- Guideline 41: there should be an immediate moratorium on bio-prospecting contracts with indigenous peoples until they and their communities are capable of supervising and collaborating in the research process.
- Guideline 56: indigenous peoples and their representative organizations should enjoy direct access to all WIPO organizations and the WTO to share their views on ways to improve the protection of their heritage through international law.

The recitation of these principles and guidelines provides a fairly complete picture of how the Working Group has positioned itself in the UN system on this debate. While there are some uncertainties in the language of the text, there is no doubt that these views are well weighted to the indigenous views. Indeed, the draft is clearly identified as drawing from two indigenous peoples declarations on the subject.¹⁰³ The Special Rapporteur, however, also took the time to stress that

¹⁰³ These are the Kari-Oca Declaration of the World Conference of Indigenous People on Territory, Environment and Development, Kari-Oca, Brazil, May 1992; and the Mataatua Declaration of the First International Conference on

indigenous peoples were willing to share their knowledge with all humanity, providing their rights to define and control it were protected by the international community.

Turning to the second document, the Draft Declaration on the Rights of Indigenous Peoples,¹⁰⁴ it contains 45 articles, including at least seven of direct relevance to the present issues. Without undertaking as extensive a review as in the previous case, these Articles would require,¹⁰⁵ if adopted,

- recognition of the right to maintain their cultural traditions and customs, including past and future manifestations of their customs, as well as restitution of cultural and intellectual property taken without free and informed consent or in violation of their laws. (Art. 12)
- the right of indigenous people to participate fully at all levels of decision-making on matters that affect their rights. (Art. 19)
- the right of indigenous peoples to participate fully in devising legislative or administrative measures that may affect them. (Art. 20)
- the right of indigenous peoples to their traditional medicines and health practices, and to the protection of vital plants, animals and minerals. (Art. 24)
- the right of indigenous peoples to own, develop and control their lands including the flora and fauna and other resources which they have traditionally owned or occupied or used; and the right to effective measures by states to prevent interference with, alienation or encroachment of these rights. (Art. 26)
- the recognition of the full, ownership, control and protection of their cultural and intellectual property, including the right to special measures to control, develop and protect their sciences and technologies, including human and other genetic resources, seeds, medicines, knowledge or the properties of flora and fauna, etc.. (Art. 29)
- the right to determine and set priorities for the development or use of their land and resources, and for their prior informed consent to be obtained before a state approves any project affecting their lands or resources. (Art. 30)

Cultural and Intellectual Property Rights of Indigenous Peoples, Whakatane, New Zealand, June, 1993.

¹⁰⁴ E/CN.4/Sub.2/1994/2/Add.1, 20 April, 1994.

¹⁰⁵ "Require" is being used in the political sense here. Adoption of a "Declaration" would not, in and of itself, create a legally-binding obligation.

In addition, there are several provisions that relate to the guarantee of legal or other procedures for the enforcement of these rights in a manner that recognizes the cultural differences between indigenous and other peoples.

As is the case with the preceding Principles and Guidelines, many of these provisions are reflective of the objectives associated with the Biodiversity Convention, but go beyond its specific legal requirements. Further, while as a whole they appear to be reflective of the general indigenous approach, there is some degree of ambiguity and "UN-ease" contained in the text that will either require clarification or will reflect, at the end, the inability to achieve more specific results in the process. As but one example, there is no clarity to what the notion of "special measures" referred to in the context of Art. 29 would mean. Both minimal and expansive views of such measures could be taken.

In 1994, the draft Principles and Guidelines were submitted to UN member governments, indigenous peoples organizations, specialized agencies of the UN and NGOs for comments. A revised set of draft Principles and Guidelines is expected later this summer from the Special Rapporteur.

The Draft Declaration was forwarded in 1994 to the UN Commission on Human Rights. At its February, 1995 meeting, it directed the establishment of a Working Group of states to review and consider the draft text. This meeting took place in November, 1995, and decided to use the Draft Declaration as a basis for negotiations on an eventual Declaration. The next meeting on this will likely be in November, 1996. Parallel to this, the Working Group on Indigenous People will continue to meet and review comments from UN members on their report, including the proposed principles and guidelines on cultural properties.

These two related efforts show a strong tone being set in this branch of the United Nations on the indigenous knowledge issues raised in the Biodiversity Convention. Substantively, it highlights the human rights-based approach to dealing with these issues, an approach now gaining strength in the NGO sector in particular.¹⁰⁶

On the organizational side, the potential visibility brought to these issues by both products of the Working Group can be harnessed to develop and support a political constituency. This dimension is added to by the initiation of the Decade of Indigenous Peoples in December, 1994. In addition, both the Draft Declaration and the Working Group on Indigenous Peoples have called for the establishment of a permanent, high-level UN body on indigenous peoples issues, with their full access and participation. Such a body would clearly work to support the direction established

¹⁰⁶ As an addendum here, the dissemination of this approach is also seen elsewhere in the Human Rights programs of the UN. For example, the Fourth World Conference on Women, to be held in Beijing, Sept., 1995, includes an item in the draft Program of Action being developed for the Conference on safeguarding the intellectual property rights of indigenous women in relation to traditional medicines, biodiversity and indigenous technologies. Specific reference to the Biodiversity Convention is made in this regard. (Para. 253 of the draft Program of Action, Fourth World Conference of Women.)

by the two key documents. A decision on this has been deferred, with one factor being the relationship of such a body to existing bodies in the context of a general UN moratorium on the establishment of new institutional mechanisms. Examples of failures to meet the political, if not fully legal commitments of the Biodiversity Convention towards indigenous peoples will likely be used to show the need for the body to be established.

5.2.4 OECD

The Organization for Economic Cooperation and Development had not focussed directly on the implementation of these Biodiversity Convention issues until earlier this year. Considering that climate change has been on the OECD agenda for several years now, this again reflects the lower overall profile of the Biodiversity Convention. As of November, 1995, the Secretariat was awaiting completion of a report cumulating responses to a questionnaire circulated to all OECD countries in March on the steps taken or anticipated in terms of access to genetic resources by their nationals and industries, as well as issues related to the sharing of benefits following such access. This effort was apparently motivated by a Swiss desire to consider the possibility of developing some form of common or coordinated responses to the Convention through the OECD.¹⁰⁷ A meeting of OECD countries on the issues is planned for Australia early in 1996.

5.3 Non-Governmental Organizations

5.3.1 Environmental Organizations¹⁰⁸

In many ways, environmental groups have been the most visible side of the "demand side" on biodiversity issues for over a decade. The role noted previously in this report of the International Union for the Conservation of Nature (IUCN) in promoting the development of the Biodiversity Convention is just one example of this. In addition, such groups as the IUCN, World Wide Fund for Nature (WWF) and World Resources Institute have been active in developing, over many years, strategies and programs from an ecological perspective for the conservation of biodiversity.¹⁰⁹

¹⁰⁷ The Swiss, it may be recalled, noted at the adoption and signing of the Convention the need for a commercial, contractual, basis for the transfer of all privately held technologies. They also noted the possibility of greater flexibility in dealing with publicly held patented technologies to meet the objectives of the Convention.

¹⁰⁸ This section, in particular, is based on the off-the-record interviews conducted by the consultant. It is, as a result, often generalized or impressionistic in nature, while fully reflecting the input received.

¹⁰⁹ These include, for example, the 1980 *World Conservation Strategy*; *Caring for the Earth, 1991* and *The Global Biodiversity Strategy, 1992*. Each of these represents a collaborative effort between the IUCN, WWF, WRI and/or UNEP.

Today, the number of environmental groups active in the Biodiversity process has expanded significantly from what it may have been even a decade ago.¹¹⁰ With this, has come the development of new global linkages among the groups, such as the Global Biodiversity Forum. Organized in 1993 by the IUCN, WWF, UNEP and the African Centre for Technology Studies, the Forum acts as a networking, information sharing and position development setting for the participants. It is not intended to provide one global voice, but a means to develop the substance and effectiveness of the many voices that compose its membership. Within this context, the full range of issues associated with biodiversity conservation, from the scientific and technical to the indigenous and intellectual property issues are brought forward. (Global Biodiversity Forum, 1994)

In addition to strategies on the broad scale and the interaction of the environmental groups, major international organizations are also actively involved in the development and funding of specific biodiversity conservation programs and activities. These include the shift from pure conservation programs to integrated conservation/sustainable use plans. Regionally and locally, this involvement extends to other environmental groups active at these levels. For example, it is estimated that of the biodiversity related projects sponsored by the Global Environmental Facility in its initial phase, 88% showed involvement of national or international environmental groups. This is the highest for any category of GEF funding. (Johnson, 1994)

In terms of the intellectual property issues raised by the Biodiversity Convention, three separate issues appear high on the ENGO list:

- the link of these issues to technology access and transfer;
- the rewarding of indigenous and traditional communities' contributions to the conservation and sustainable use of biodiversity, i.e., the intellectual property of these communities; and
- the patenting of life forms.

Each of these has a link to GATT and the TRIPS Agreement. The potential institutional concerns created by the linking of the intellectual property issues to the two agreements are discussed in Part 2, above.

Technology transfer is understood as fundamental to achieving the objectives of the Convention. The related IPR issues are generally raised in the context of Art. 16(5) of the Convention, and are often described or implied as the obligation to ensure that in the event of any conflict, the conservation of biodiversity shall take precedence over IPRs. (eg., WWF, 1994, p. 33) A significant part of the concern stems from the belief that IPRs will not assist in the transfer of technology: as TRIPS now demands the putting in place by all parties of IPR regimes that were developed almost uniquely in a Northern context, and that do not reflect the development conditions of the South, it is asserted they will negatively impact on the ability of developing countries to obtain important technologies, or develop domestic industries with leading edge technologies. A

¹¹⁰ For a broad review of this expansion, see, eg., Section 7 of Krattiger, et. al., 1994, on the role of NGOs and other institutions in the implementation of the Biodiversity Convention.

full study of the impact of IPRs on the operation of the Biodiversity Convention, under the auspices of the Convention, is seen as required by many groups. (Nijar and Ling, 1994; WWF, 1994; BioNet, 1994) A second major concern is that the technology transfer provisions outside the context of an access arrangement will lose priority in the implementation of the Convention. Accompanying this is the concern to build functional and effective institutional mechanisms for the transfer of technology, including a clearinghouse mechanism to enable easier identification of, and access to, technologies.

The original concern of the major environmental groups in relation to the rewarding of local and indigenous knowledge can be traced to the recognition of the role of local communities in the conservation and management of biodiversity.¹¹¹ With the identification of indigenous and traditional peoples as the prevalent type of local community in the world's most biodiverse areas, the full articulation of this link developed through the UNCED process: the conservation of biological diversity was dependent on the effective maintenance of cultural diversity, and the maintenance of cultural diversity in turn relied on the diversity of the resources that the lifestyles depended on. Thus, the need to ensure suitable incentives to maintain biodiversity was identified, including intellectual property rewards, to counterbalance the alternative uses that could be detrimental to biodiversity and cultural conservation. The link between sustainable local and indigenous communities and biodiversity has developed into a corner-stone of the post-Rio period for environmental groups. (Global Biodiversity Forum, 1994, pp. 12-16)

The conservation aspect of incentives has been accompanied by a growing appreciation of the human rights issues associated with indigenous and traditional intellectual property rights. When linked with the work of the Working Group on Indigenous Peoples, this dimension is rapidly emerging as a powerful motivating factor within the environmental community. Views in this area now include groups who see the rewards issue as secondary to the rights issues: the self-determination of the indigenous peoples, and the right for them to control their cultural and intellectual property is defined as central to the inherent rights of indigenous peoples.¹¹² Rewards would follow as a natural result of such control. One suggestion also includes the creation of a fund for the deposit of all negotiated or volunteered financial benefits following access, to be used for conservation purposes. This, it is argued, would not impose Northern financial considerations on cultures not desiring to deal with them, and could eliminate competition between groups sharing similar resource attributes.

Associated with this trend is the identification of access agreements as the foundation of the international link between access to the genetic resources, the protection of local and indigenous rights to control and benefit from access to their areas and to their resources, and the sharing of benefits in financial and technology-based terms. Thus, for example, the Third World Network has prepared a draft national law on community rights, including full decision-making powers for access

¹¹¹ This is seen, for example, in the statement by the WWF, Informal Workshop, 1994, pp. 2-3.

¹¹² A full review of the development and present state of this issue, from a legal perspective originally commissioned by the WWF, is found in Shelton, 1995.

to their resources, based *inter alia* on national legal protections. In addition, the IUCN's Environmental Law Centre has actively assisted the Andean Group in the development of their recent Decision on access to genetic resources among this biodiverse rich regional group. As noted in the Andean Group report, this included a process of local indigenous group and environmental group participation in the development of the formal Decision. Other groups are in the process of preparing model contracts or laws on access issues.

Most environmental groups support the need for some type of legally-binding instrument in the area of access. Many also concede, however, that the attainment of this goal will not likely be possible while the biosafety issue continues to occupy both negotiating and political energy as the central focus of the first years of the Convention's operation. There can be no question, however, that the negotiation of any type of instrument under the Convention will not be seen as legitimate by the environmental groups unless there is full participation of indigenous peoples' representatives.

In the interim, the development of bilateral agreements will be followed closely by most environmental groups, as will the implementation of what are seen as the obligations of the developed states in regulating access to foreign resources by their nationals. Expanded ENGO support to developing countries in the preparation of bilateral agreements in this area can be anticipated.

Beyond the access issue, there is also the clear recognition that the TRIPS Agreement does not support the rewarding and protection of indigenous knowledge. One major suggestion here is for developing countries to utilize the full implementation period granted them under TRIPS prior to implementing any of the IPR regimes required by the Agreement. This period should then be accompanied by a process of defining a mechanism for the international protection of these rights that is also consistent with the types of practices and processes, including communal ones, that constitute the basis of traditional and indigenous knowledge and scientific and technical innovation. (eg. WWF, 1994; Caillaux, 1994)

As an aside here, the utilization of the legal resources and facilities of the major environmental groups is becoming a feature not just in the drafting of laws or regional agreements, but also on the litigation side. For example, the Sierra Legal Defence Fund has been behind much of the litigation to support indigenous land and environmental rights claims in Ecuador in response to oil company operating permits in sensitive environmental areas. Some of the claims in this type of litigation would also support indigenous claims to biodiversity resources if successful. These actions have been both domestic and international in nature. (Aguilar and Popovic, 1994, p. 198) They represent a "bottom-up" approach to the issues that complement the international positions and efforts of the environmental community.

The patenting of life forms continues to be a serious concern among environmental groups. Third World Network, the leading developing country group in this area, has continued to oppose the patenting of life forms since the conclusion of the Biodiversity negotiations. (Shiva, 1995) Many Northern, especially North American, environmental groups have been less focussed on this issue, but are now picking it up. Some, have followed the TWN position. (eg., Blue Mountain

Declaration, 1995) Others, such as the Canadian Institute for Environmental Law and Policy, have shown concern for the lack of informed public debate on the full range of potential consequences of patents on life forms as a key element of concern. However, some groups, while not accepting the premise of patents on life forms, have participated in processes that include, as part of the full scheme, the recognition of intellectual property rights on genetically modified life forms as the basis for the financial benefits that would be shared following an access agreement. Generally, however, the environmental movement continues to oppose patents on life forms.

The Human Genome Diversity Project remains a strong uniting point for ENGOs and indigenous peoples' groups. This is due in part to the opposition to patents on life forms that many fear the Project will lead to. It also reflects concerns for the perceived abuse of indigenous peoples in the taking of their genetic material, often without informed consent. This has strong links with the rights based view of indigenous resources and intellectual property, and the link between the two.

The TRIPS Agreement is again relevant here. With the Biodiversity Convention silent on the requirement to patent life forms or not, TRIPS becomes a major target for those both opposed in principle and those opposed to IPR schemes that only recognize Northern conceptions of the development of life forms that can be subjected to such protections. It is clear at this time that most environmental groups will be focussing on the four year review period of Art. 27.3(b) of TRIPS dealing with the patenting of life forms. They have also, successfully, focussed on the rejection of national legislation relating to this element of TRIPS in many jurisdictions, including India and the European Community.

The final area of major concern is the institutional roles of the Biodiversity Convention and the WTO, in particular the roles of the Trade and Environment Committee and the TRIPS Agreement. Several environmental organizations in the North and the South have expressed concern that international trade law is developing in a manner that is not supportive of environmental issues or sustainable development more broadly. The full debate is well beyond the scope of this report. What is important here is the identification by the WTO of TRIPS and the environment as a separate agenda item for the Trade and Environment Committee, as noted in the section above on the WTO. This provides a focus to the concerns that many groups have that the Biodiversity Convention not play "second fiddle" to TRIPS. The substantive areas of concern have already been noted, including the four year review of Art. 27.3(b). In addition, there is likely to be a strong focus on the "performance" of the North in transferring technologies to the South under the Convention. Apparent shortcomings in this regard, from the developing country perspective, will garner strong responses in terms of the relationship between the two conventions and the need to take measures to make intellectual property rights more supportive of the goals of the Biodiversity Convention. Such shortcomings, if they are seen to materialize, could also impact on how the broader, still presumptive, issue of the impact of IPRs on technology transfer to the South is developed in both the WTO and environmental fora.

There is a strong desire for the relevant issues to be addressed in the context of the Convention framework, rather than the WTO setting. However, there is also a strong concern that the institution that "counts" is the WTO. This is for two reasons. First, with the lessening of international environmental attention since UNCED, the focal point of governmental decision making is seen to reside in the economic ministries represented at the WTO. Thus, these are perceived as the "real" decision makers by many observers from the environmental side. Second, the WTO includes a binding dispute resolution process that essentially does not permit considerations from environmental agreements to be brought in. The Biodiversity Convention contains no such binding process, though it does have an optional binding arbitration annex and a mandatory conciliation annex. Further, the WTO process allows for trade sanctions in the event a breach is found, which the Biodiversity Convention does not. In short, the WTO is seen by several groups to have more teeth, at least at this time, than the Convention.

These factors, as well as the general profile of the trade and environment issue, have placed a high concern on the role of the WTO in this area. It is one that will be watched carefully by environmental groups.

5.3.2 Indigenous Peoples Organizations

This particular non-governmental sector has emerged only recently at the international level in relation to these issues. Still, one cannot help but note that the list of NGO participants at the first COP in November, 1994, included at least eight indigenous peoples organizations, as well as the many environmental groups that place a high emphasis on indigenous issues.

Indigenous participation in the development of the biodiversity/IPR issues is supported by the text of Art. 8(j) of the Convention, and the broader reference to Agenda 21 and the Rio Declaration. It is also now supported by the initiation of the International Decade of Indigenous Peoples by the United Nations, noted above. These elements will provide a sound political framework to support the increased participation of indigenous groups in the development of programs, principles and other documents relating to the use, protection and rewarding of their knowledge.

Since the beginning of the UNCED process, major indigenous peoples declarations relating, in part, to the issues in the Biodiversity Convention have emerged. Two that lay at the heart of the draft Principles and Guidelines discussed above have already been noted, the Kari-Oca Declaration, Brazil, 1992 and the Mataatua Declaration, New Zealand, 1993. The latter conference, for example, included over 150 delegates from fourteen countries. Other similar regional and global conferences have been held, and different statements or declarations prepared.¹¹³ These Declarations focus on the inherent and exclusive rights of indigenous peoples to their intellectual and cultural property,

¹¹³ For example, the Kari-Oca Declaration was preceded by the "Charter of Indigenous-Tribal Peoples of the Tropical Forests", Penang, Malaysia, Feb. 1992.

to control it, benefit from it, share it on their terms, and to the exercise of full rights of prior informed consent. As is the case with the official UN documents, they take a strong human rights-based approach to the issues, and include the physical resources themselves within the conception of their intellectual and cultural property. Indigenous groups are uniformly against the concept of patents on life forms, as well as the inequity of the conceptions of intellectual property in this area. The Human Genome Diversity Project is a virtual lightning rod in this area.

Greater organizational efforts among indigenous groups in relation to these issues are now materializing. The Mataatua conference, discussed above, is one example. This type of gathering is now increasing in scope and frequency. Just as importantly, the follow-up to the Mataatua Declaration has included institutional development, the establishment of the Indigenous Intellectual Property Rights Centre in Whakatane, New Zealand. This Centre is associated with the Indigenous Peoples Biodiversity Network (IPBN), whose coordinating office is located in Ottawa.

In addition to the organization of indigenous peoples' groups inter-se, there is a growing interaction with other groups, environmental in particular, that is spawning a broader political and public network on these issues. This is being supported by the Working Group on Indigenous Peoples and the UN Centre for Human Rights. For example, a major "informal workshop" on the subject was jointly sponsored in July, 1994, by the International Academy of the Environment, IUCN, WWF and the UN Centre for Human Rights. This is a significant reflection of the type of coalition building with and by indigenous groups presently being done.¹¹⁴

The response to the challenges of the IPR issues are focussed not just on the Biodiversity Convention, but also on the WTO. Legally binding protocols are an identified goal. Ultimately, the development of the right to self-determination is seen, at least by some, as the touchstone for the protection of indigenous rights of all types. (Informal Workshop, 1994, p. v)

Finally, in addition to the growing international activism and organization, activity at the national level by national and international indigenous groups is emerging as a critical part of the process of clarifying and obtaining indigenous rights. Again, this is often done with the support of environmental groups, especially legal groups. The number of countries reported on in the preceding country reviews where this has occurred provide very ample evidence of this trend, and the existing and potential role of Biodiversity Convention issues in its development.

5.3.3 Business Organizations

At the non-governmental level, organized business activity appears to be the least developed of the three NGO sectors discussed here. The only exception to this is more one of the perception of the organized rejection of the Convention by the American biotechnology sector. This rejection, it should be noted, is far from solid today, if it ever was solid, although the US clearly is unlikely

¹¹⁴ This meeting is reported on in Informal Workshop, 1994.

to ratify soon. (Hoyle, 1994; Coughlin, 1993; I.E.R., 1994) Bilateral activity between biodiversity rich countries and American companies and institutes continues to develop, as seen in the country reviews above. Indeed, in many ways, these US companies and bodies have taken the lead in meeting the challenge originally launched by Merck & Co. on the business side to meet the goals of the Convention.

While sectoral groups remain concerned with the developments in many areas of the Convention relating to intellectual property rights, the growing recognition of the contractual model for entering into agreements has reduced much of the original anxiety. In short, the roof has not caved in with the coming into force of the Convention. In addition, the rapidly improving means to develop both genetic and chemical products for specific purposes in a laboratory setting has been identified by some businesses as reducing the need for access to resources. This in turn is seen to reduce the commercial value of the resources, and thus the demands that might be anticipated in the event an access agreement is deemed desirable. Both these factors may be contributing to a more muted business response, on a global basis, to the Convention than might have been anticipated.¹¹⁵

Professional associations, including ethnobiologists and bio-prospectors, form another group which has pursued an interest in this area. Indeed, some would suggest they have taken a lead role in devising codes of conduct that are specifically relevant to the issues related to the identification, use and rewarding of indigenous knowledge. The first voluntary code of conduct was adopted by the International Society of Ethnobiology, in the July, 1988, Declaration of Belem. It established a set of principles for interaction among its members and indigenous peoples, and included the first "call" at such a level for the just compensation of the use of indigenous knowledge as well as protection of indigenous intellectual property rights. Asian scientists produced a similar "Manila Declaration Concerning the Ethical Utilisation of Asian Biological Resources" in February, 1992, as discussed above. Guidelines or draft guidelines have also been produced by the Society of Economic Botany, and the Society for Applied Anthropology.¹¹⁶

These declarations and codes are designed to create a potential operating framework for all members of the profession. Thus, they serve to heighten awareness and reform conduct, when implemented effectively. The Declaration of Belem was one of the main instruments in raising academic and subsequently public attention to the issues at the end of the 1980s. To the extent that this arm of the biotechnology sector ensures respect for and protection of indigenous knowledge, as called for in the codes, other arms of the business may be pulled along.

¹¹⁵ As but one example of this, the World Industry Council for the Environment was an NGO participant at the first Biodiversity Convention COP. It has now merged with the Business Council for Sustainable Development to become the World Business Council for Sustainable Development. This multi-sectoral organization has the Climate Change Convention as a full work program item at this time. The Biodiversity Convention, by contrast, is on an "environmental watch list". Source: World Business Council on Sustainable Development, 1995.

¹¹⁶ Referenced in Note of the Interim Secretariat, Biodiversity Convention, "the rights of indigenous and local communities embodying traditional lifestyles: experience and potential for implementation of Article 8(j) of the Convention on Biological Biodiversity", UNEP/CBD/IC/2/14, 20 May, 1994, p. 19.

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6.0 CONCLUSION

It is difficult to draw conclusions in this study. First, there is a risk that, by focusing on a limited number of regions, the study over-emphasizes a development and thereby "discerns" a trend when none really exists. Further, it is difficult to reach conclusions in a field where concepts and instruments are still in a formative stage.

The Biodiversity Convention has brought about a shift in approach among the resource-rich nations toward their resources, and toward the protection of both the tangible and the intangible rights in those resources. While the "common heritage of mankind" principle is not dead -- it is still present in the 1983 Undertaking on Plant Genetic Resources which, at least until the revision is complete, continues to apply to certain plant genetic resources for food and agriculture -- it is evident that the "common concern" and "national sovereignty" approaches to genetic resources are being applied throughout the countries surveyed, at least to their *in situ* genetic resources. Even within the FAO, these principles are setting the parameters of the discussion for the revision of the 1983 Undertaking, and indeed have already been adopted for certain situations, as under the Code of Conduct for Plant Germplasm Collecting and Transfer.

Several common features of the various national initiatives to exercise this national sovereignty over genetic resources may be noted. First, recognizing that national sovereignty and ownership are distinct, most of the countries surveyed have declared the genetic resources within their territorial boundaries to be part of the "national patrimony", or otherwise have vested ownership of the resources in the state. (See, for example, the Andean Pact proposal; Costa Rican law; Cameroon (arguably, the OAPI Agreement also does this); The Gambia (it is unclear how far this provision goes to asserting national ownership of the genetic resources); the Philippines; Indonesia (under the LIPI rules); and proposed legislation in the Queensland, Australia.)

The full implications of such a declaration remain to be seen. While some of the declarations vesting ownership of particular, defined resources in the state are relatively unambiguous, the scope of a general assertion providing that "genetic resources" belong to the state is less clear. On its face, such a declaration could be said to go very far, transferring all rights to all genetic resources to the state. Presumably, though, the intended purpose is more limited, namely to ensure both conservation of the resources, and an appropriate economic return to the state from any subsequent commercialization activities. It may be that in fact such declarations are effecting a split of rights in genetic resources, dividing control over the intangible information, and access to the tangible specimen for purposes relating to the intangible information, from other rights in regard to the tangible specimen. It will be interesting to see how such declarations are applied in practice.

At the same time that genetic resources are deliberately placed under national sovereignty, there is evidence of substantial international cooperation in determining how that national sovereignty should best be exercised. The survey disclosed a number of instances of bilateral cooperation, sometimes formalized under bilateral agreements (e.g., the Mexican agreements with each of Australia, Cuba, Costa Rica and the United States), and sometimes manifested in less formal collaboration agreements (e.g, INBio's collaboration agreements with Kenya and Indonesia). The

importance of common regional policies on bioprospecting is recognized, as is clear from the regional roundtable discussions.

The proposed Andean Pact Common Regime on Access to Biogenetic Resources would take international cooperation and reciprocity to a higher level: as originally proposed, member states would be required to "cooperate with other States and promote reciprocity through the adoption by those States of appropriate national legislation in conformity with the Convention on Biological Diversity." This is particularly noteworthy in view of the express linkage under the Andean proposal between intellectual property rights and prior informed consent. Andean Pact countries -- the repositories of rich reserves of biologically diverse genetic resources -- may thus require reciprocal treatment from countries seeking access to these resources. That is, that any country seeking access to the physical resources agree to demand proof that the access was obtained with the requisite prior informed consent (e.g., the Certificate of Origin under the Andean draft), before granting or enforcing intellectual property rights relating to those resources.

The Andean initiative was the most far-reaching, in terms of intellectual property rights, of those surveyed for this study. It is very possible that the Andean draft will influence the direction of other national policies and legislation, as well. Particularly as scientific advances reduce the importance of access to the tangible specimens, as smaller and smaller quantities are required for genetic analysis, the importance of a linkage to the intangible information obtained therefrom increases dramatically. Thus the granting or withholding of rights in the intangible information becomes the key to asserting sovereignty over the resource itself -- both the tangible and intangible elements thereof -- and to obtaining the sharing of benefits, envisaged by the Biodiversity Convention.

Access agreements, modelled on the INBio examples, are now the norm among the countries surveyed. Indeed, in Indonesia we learned that the terms of access agreements have in effect replaced the access rules "on the books", which have yet to be updated to keep pace with the current terms of access being applied "on the ground". The terms of these agreements generally control access to the tangible resource, and provide for benefit-sharing through some combination of up-front payments, technology transfer and royalty payments from any subsequent commercialization. Our survey has not disclosed extensive use of terms that seek control over the intangible information relating to the resource. However, it should be noted that a number of the countries surveyed are still developing intellectual property regimes that could protect such intangible rights. As the legal framework evolves -- for example, to implement obligations under the TRIPs chapter of the recent GATT agreement -- this may change, as well.

It is too early to know whether these agreements will have the desired effect. Some critics have questioned whether these agreements adequately inform about the potential value of the genetic resource, raising the question whether they truly fulfil the requirements of constituting "prior informed consent". Financially, we do not yet know whether the rewards of cash, royalties and technology transfers to the source countries will meet the high expectations. It is also too soon to know whether the conservation goals will be achieved. Some of the concerns expressed -- for example, the different time frames of access agreements (short term) and conservation (long term) --

remain largely unaddressed. Hopefully these are issues which will be resolved, as more experience is gained.

Finally, indigenous and local communities are playing a substantial role in the development of policies and legislation on genetic resources. Both the Andean Pact proposal and the recent Philippine Executive Order on bioprospecting contain provisions to ensure that indigenous and local communities are involved and protected in any bioprospecting decisions, and receive appropriate compensation.

The nexus between biodiverse genetic resources and developments in biotechnology may be reshaping the fabric of international politics, as the different interests converge and complement one another. The revolution set in motion twenty years ago is not yet over; whether it will fundamentally transform traditional notions of property rights, or whether the focus will remain with contractually-determined rights, remains to be seen.

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APPENDIX A:

The questionnaire used for this study.

Questionnaire

1. Practical Experience with Biotechnology Projects

We are trying to learn what is actually going on in various countries around the world with on-going projects, or what is intended to be done with future projects. In particular, we would like to learn **who is involved** in setting the terms for biotech research and development, and **the sort of terms** that are being used. To this end, we would like to learn about the following aspects of the biotechnology projects (projects related to the discovery or development of genetic resources) with which you are familiar that have taken place, or are taking place in your country. (Please feel free throughout to write comments on additional pages, where there is insufficient space.)

(a) Who has been involved in setting the terms for the project, for example, granting access to genetic resources, setting the terms of any technology transfer, compensation, etc.? (You may check more than one, but your comments explaining generally how each is involved, and to what extent, would be appreciated.)

☐ government

☐ your government

☐ another government (please specify nature of interest, eg, funding research; home country of business conducting research, etc)

☐ private business, patent holders

☐ indigenous/ local community groups

☐ non-profit organization (please describe the general type: research, etc.)

☐ university

☐ other (please describe)

Comments:

(b) In your opinion, has this level of involvement worked effectively? Or are there other arrangements you think would be useful, and why?

(c) What terms or conditions are used generally for gaining access to and use of genetic resources in your country? (Again, you may check more than one.)

☐ informed consent

☐ compensation

☐ one-time or repeated fee for entry to area where genetic resources are located

☐ profit-sharing or ☐ royalty-sharing arrangement for any patents or other intellectual property that results

☐ other (please describe)

☐ information sharing, eg disclosure of results of research (please describe)

☐ transfer of technology (discussed more below)

☐ ownership of genetic resources (the physical specimens, not intellectual property rights)

☐ owned by scientist/company seeking to use the resource

☐ owned by your government

☐ owned by private citizen who owns the land

☐ owned by other (please describe)

☐ other (please describe)

Comments: (Please include your opinion whether these terms and conditions work effectively, or what other arrangements in your opinion would be useful.)

(d) If transfer of technology or intellectual property rights are terms or conditions used before granting rights of access to or use of genetic resources, please check the categories that best describe the arrangements used:

☐ licensing of intellectual property rights to technology developed from the genetic resources

☐ patents

☐ trade secrets

☐ plant variety protection

☐ other, eg. copyright, trademark, etc. (please describe)

☐ only in your country, or ☐ worldwide, or ☐ other (please describe)

☐ assignment of intellectual property rights to technology developed from the genetic resources (Please describe the type of intellectual property rights: patents, plant variety rights, etc.)

- ☐ outright assignment
- ☐ partial assignment (eg, establishment of a joint venture)
- ☐ other, eg. royalty-sharing, etc. (please describe)

-
- ☐ only in your country, or ☐ worldwide, or ☐ other (please describe)
-

☐ licence or assignment to: _____

☐ other, eg education and training, exchange of information, financial support of other research projects, establishment of joint ventures, etc. (Please describe)

Comments:

(e) In your opinion, have these arrangements worked effectively to:

(i) encourage research and development in the field of biotechnology

- ☐ very effectively: extensive research and development
- ☐ moderately effectively: research and development is proceeding well, but could be more
- ☐ acceptable but needs improvement: there is some research and development, but there could be much more
- ☐ unacceptable: there is very little on-going or new research and development

(ii) encourage conservation and maintenance of biological diversity in your country

☐ very effectively: significant amounts of land and/or *in situ* genetic resources have been specially preserved to maintain a guaranteed base for future prospects; monitoring is in place

☐ moderately effectively: some prospects for biodiversity preservation are in place in either the public or private sector, and there are on-going processes to develop other projects as well as a broader policy

☐ some effect: some experimental/pilot efforts have been undertaken, but there remains little coordination among the relevant sectors, and little policy work being done

☐ no relationship between conservation of biodiversity and the rewards from access to, or use and development of genetic resources exists in any practical way

(iii) result in an equitable sharing of economic benefits

☐ satisfactory: you feel satisfied that these arrangements have provided each organization involved with a satisfactory economic benefit

☐ acceptable: there has been some economic benefit to each organization involved, although lower than that obtainable elsewhere

☐ uncertain: it is unclear whether the economic benefits justify the project

☐ unsatisfactory: there has not been adequate sharing of economic benefits

(iv) If there are other social, political or economic objectives that are relevant to these arrangements, which are not covered above, please describe:

Comments. (Please include any suggestions of other arrangements that you feel might help any perceived shortcomings.)

(f) How would you compare the role of intellectual property rights to other mechanisms (eg, maintaining common property, publicly-funded research, debt-for-nature swaps, direct conservation such as parks) in promoting:

- (i) the development of the economic potential of biodiversity;
- (ii) the preservation of biodiversity;
- (iii) other social, political or economic objectives that may be relevant.

(g) Do you have any comments or suggestions with respect to the process of negotiating access or use arrangements? Do you have suggestions or models you would recommend to improve the process in the future?

2. Legal and Policy Context

(a) Are there laws or policies in force in your country that regulate terms of access to or use of genetic resources? Any information you can provide about these laws or policies, or suggestions how we can obtain information about them, would be extremely helpful.

(b) Are you aware of any studies or proposals for laws or policies in your country, to regulate the access to or use of genetic resources? Any information you can provide about these studies or proposals, or how we can obtain information about them and their status, would be extremely helpful.

(c) Could you comment on the effectiveness of these laws, policies and proposals in terms of protecting biodiversity, encouraging research and development of biotechnology, and promoting other relevant social, political and economic objectives? (If you are aware of concerns that are being expressed by certain groups about the effectiveness of some of these laws, policies or proposals, we would appreciate hearing about them, even though you may not personally share these opinions.)

3. Other Contacts

If you can suggest other individuals -- in your government, non-profit organizations, the private sector, or in indigenous groups -- whose input you believe would be helpful to our study, please let us know. (Telephone and fax numbers would be particularly helpful.)

4. Literature Review

We are currently in the process of reviewing the literature dealing with these issues. If there are particularly useful current articles, books or reports on these issues, especially with respect to your country, that you would recommend, we would appreciate your suggestions.

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The biodiversity convention, intellectual property rights, and ownership of genetic resources international developments

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