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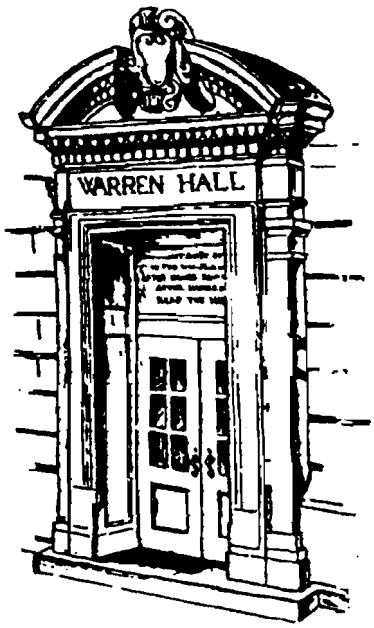

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INTERNATIONAL TREATIES AND OTHER LEGAL AND ECONOMIC ISSUES RELATING TO THE OWNERSHIP AND USE OF GENETIC RESOURCES

by

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ABSTRACT

Genetic resources were once treated as a common heritage, available without restriction for research and other usage. The system was perceived as contributing to a rapid extinction rate and as unfair to developing countries — the major source of genetic resources. Since the Biodiversity Convention declared that governments have the "sovereign right to exploit" the genetic resources under their domain, efforts to regulate access have begun. Conceptually, payments will lead to greater conservation efforts; practically, the incentive will depend on use and distribution of the limited funds generated. Benefits to countries of origin are associated with the "equitable sharing" stipulations of the Convention. Within countries, where rights of indigenous peoples to their traditional lands have not been clarified, equitable sharing may be difficult to achieve. To date, a limited but potentially troubling effect has been a slowing of access, especially for third parties. Current approaches to access include i) Intellectual Property Rights (a system not attuned conceptually or practically to genetic resources); ii) Farmers' Rights (a system grouping agricultural genetic resources transferred in the past, present, and future); iii) Bilateral Systems, such as material transfer agreements in place (Philippines) or in process (Andean Pact); and iv) Multilateral Systems, as endorsed by the FAO and outlined by IPGRI. A truly effective system(s) for access to genetic resources has not yet emerged; it is time for wider inputs into the process, especially by biological scientists.

I. INTRODUCTION

Technological advances create uses for previously unvalued resources. Not until Marconi's work on the wireless a century ago did the airwaves acquire practical value. In the case of the U.S. government, it was only very recently that rights of access were sold rather than given in the name of public benefit. Regulations similarly create value where none existed. When the decision was made that pollution (or more correctly effluent) permits were tradeable, a market quickly emerged. Now there is even talk of creating an indirect market in the form of a futures contract.

Over the past several decades, genetic resources have been affected by both these forces. First, scientific plant breeding dating back roughly to Marconi's time and, within the past 20 years, biotechnology, have created uses for, and hence value of, genetic resources which previously did not exist. Administratively, Plant Breeders' Rights (PBR) in the 1960s/1970s and patented plants in 1985 provided the opportunity to capture much of the value created. Then in 1992 the

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Convention on Biological Diversity declared exploitation of genetic resources to be the sovereign right of the country where the resources occur. These represented fundamental shifts from perhaps 12,000 years during which genetic resources moved openly, and 15 years when they were formally identified as the "common heritage of mankind."

It is no wonder that users and suppliers of genetic resources are reeling from all these changes, and are uncertain of what the future may hold. Here I shall attempt to identify the major means of exerting control over genetic resources and the consequences of each for users and suppliers. The system remains very much in evolution, but enough is evident at this point to identify the trends and assess in a preliminary way their interactions and consequences. Overall, I conclude, not surprisingly, that the perfect ownership system remains to be identified, and make some (hopefully) useful suggestions.

The major systems may be categorized as **unilateral** (patents and PBR), **bilateral** (transfer agreements, access laws), and **multilateral** (esp. CGIAR genebank holdings). Each of these has distinct implications for the assertion of ownership and use rights, not the least of which is the matter of payment. There should though be no misconception but that the form of ownership used has a direct bearing on use. Strong systems, those imparting strict rights to the owner, can, if the owner so chooses, be used to limit access. This certainly applies to patented material. However, carefully developed and long-litigated systems, again like patents, specify quite clearly the extent of those rights. In some respects new and/or vague systems are potentially more restrictive as rights have not been clearly delineated.

What I shall not attempt to discuss is how those monies are used, in particular how they might be applied as incentives for conservation of the genetic resources on which the entire system depends. As a general matter, generating economic returns from a resource provides incentives for protecting it. Generalizations aside, the effectiveness of incentives is very dependent on just how the monies are distributed. Within our own system, proceeds are often filtered into the Treasury with no clear connection with the resource, nor with those living closest to those resources. The situation in most countries is similar. Far more attention to that matter is required; I consider it both more important and difficult than the generation of value discussed here. The task nonetheless is left to others. Furthermore, I will not attempt to discuss in detail indirect implications of these systems, such as the effects of IPR on the exchange of information among researchers.

II. UNILATERAL SYSTEMS: INTELLECTUAL PROPERTY RIGHTS

Intellectual Property Rights (IPR), defined strictly, apply to five forms of law, those covering patents, Plant Breeders' Rights (PBR), trademark, copyright and trade secrets. Here my attention shall be focused primarily on patents and PBR as the most likely forms used to protect genetic resources. IPR are referred to, for purposes here, as unilateral because they are essentially national legislation with national authority. A U.S. patent allows the holder to control use, including importation, only within U.S. borders; it has no effect on Canada, Argentina, or

elsewhere in the world. There are, to be sure, a number of international patent agreements (e.g., the Paris Convention, The Patent Cooperation Treaty, the Budapest Treaty, the European Patent Convention, etc., see e.g., Bent *et al.*, Chap. 9), but they are restricted to the harmonization of national practices, or facilitate the acquisition of multiple national patents.

Applications to life forms are quite recent: the U.S. Plant Patent Act of 1930 (vegetatively propagated plants), international PBR convention 1960 (UPOV; adopted 1970 in the U.S.). But not until 1980, '85 and '87 in the U.S. was utility patent protection extended respectively to microorganisms, plants and higher animals. Most of the remainder of the world has acted slower with some 44 countries as of 1988 (WIPO 1990 App. II) specifically excluding patents for plant and animal varieties (see Crespi 1992 for a discussion of interpretation of this terminology). The last (Uruguay) round of GATT in the section titled Trade Related Aspects of Intellectual Property Rights (TRIPs; Sec. 5, Articles 27 and 39) describes a commitment of signatory countries to (among other changes):

- extend patent protection to microorganisms
- allow patents for plants **OR**
- adopt a form of PBR (technically a *sui generis* or specific law), or both, and
- provide for trade secrets protection.

Most countries appear to be opting for PBR as opposed to patents. Thus, the geographic scope of patent protection for genetic resources in the form of plants and animals is limited presently and will remain so for the foreseeable future. Trade secrets work, but only if the use of the material can be kept secret, including from independent discovery. Not only is that difficult to accomplish, it is counter to the concept of an open exchange of ideas. Prof. Barton discusses aspects of this issue elsewhere in this proceedings.

The other option is the patenting of the genetic constructs themselves. In most countries, however, the patentability of gene constructs has not been clarified. That is, the law is silent on the subject area, and no cases have been ruled on by the national patent offices. Thus the eventual outcome is uncertain, although in most countries there is no reason to anticipate a rejection. It may just take some years to reach that position.

With this background, there are two specific issues as regards the use of traditional IPR for genetic resources. These are (1) role of PBR and (2) the general impracticality of patents. These are considered next; subsequently attention is focused on non-traditional IPR systems.

A. Applicability of PBR

PBR, it can be stated categorically, are not broadly useful for the protection of genetic resources. The UPOV acts adopted by most countries with these systems (a few additional countries like Kenya and Taiwan have national systems, but their details are not readily available) are clearly directed to agriculture and floriculture applications. This is most evident from the 1961 Act where (Annex) the families and genera included are within what can be characterized as agriculture and horticulture. The 1978 and 1991 Acts are not as specific, but an application for materials from the wild with possible medicinal uses would be treated very skeptically. Certainly

C. Non-Traditional Forms of IPR

If traditional IPR is largely inapplicable, what of nontraditional forms? This would include such systems as protection of expressions of folkloric expressions and appellations of origin. Each has its particular characteristics, but a detailed discussion is not feasible here. For more information see Lesser (1994), Correa (1994), or Posey(1994).

Folkloric expressions share many of the characteristics of genetic resources in terms of distinctness for a composite of characteristics. Unfortunately, they also share the characteristic of difficulty in describing unambiguously what those unique characteristics are. Without a clear description of what is claimed as owned, no workable IPR system is possible. Indeed, the WIPO/UNESCO "model provisions" for protecting folklore were never implemented (WIPO 1985). Appellations of Origin (Lisbon Agreement of 1958, administered by WIPO) apply to products (like wine) for which local agronomic conditions contribute a distinct characteristic (like wine). For genetic resources that may or may not be the case so no systematic use seems possible.

D. Conclusions

Traditional IPR systems, patents in particular, may, where allowed by law, be used to protect some forms of genetic resources. The vast bulk of materials however will neither pass the patentability requirements or, achieving that, cost practicality considerations. PBR and nontraditional forms are not really appropriate.

III. BILATERAL SYSTEMS: ACCESS LAWS

The above conclusion, long recognized in many circles, has led to multiple calls for a new property rights regime (e.g., Keystone 1991). Until such a system is developed (I personally have doubts a broadly agreeable one will ever be identified), national access legislation will serve that function. Legislatively, access legislation draws from the authority of the Convention on Biological Diversity (CBD) Article 15(1) (emphasis added):

> Recognizing the sovereign rights of States over their natural resources, the **authority to determine access to genetic resources rests with the national governments** and is subject to national legislation.

Practically, the legislation has taken the form of Material Transfer Agreements (MTAs), effectively a contract agree upon by suppliers and users. For that reason, access laws are referred to here as bilateral systems.

In this section I shall describe the current laws, their apparent strengths and weaknesses, and conclude with my view of an appropriate extension. A brief reference to MTAs provides a convenient starting place.

A. Material Transfer Agreements

MTAs, which my colleagues tell me are commonplace in the exchange of materials in the biological sciences, typically are used for materials which have been characterized to some degree, but which are not otherwise protected by IPR (see also Sedjo and Simpson 1994). Such

agreements contain three common clauses (1) allowing use for research purposes only, (2) mandating a separate agreement be established in the event of commercial use, and (3) prohibiting sharing with third parties. Such agreements create major record keeping tasks for researchers, and sometimes commercialization agreements can be difficult to establish. On other occasions, the use conditions may be onerous - a claim to rights to anything produced from or suggested by the material - based on limited investment by the owner. But by and large, MTAs are part of contemporary science and provide a basis from which to assess access agreements.

A second comparative basis used for many specimen collection agreements is codes of conduct. Codes of conduct refer to standardized but voluntary agreements specifying obligations. They are similar to a one-sided contract voluntarily entered (compare with for example Downes *et al.* 1993). The FAO has over several years prepared a "Code of Conduct for Plant Germplasm Collecting and Transfer," still in draft form, which could serve as a model for protecting genetic materials (FAO 1993). Kew Gardens also operates under its own voluntary code of conduct.

The FAO Code, which is directed primarily to governments, has the principal objectives of promoting respect for the environment, local traditions, and cultures and establishing mechanisms for compensating local communities and farmers for their conservation and development activities (Article 1). The mechanism for achieving these goals is to require collection permits (Article 8) subjectable to certain conditions, including "financial obligations," restrictions placed on the distribution or use of the germplasm or improved materials derived from it, the use of care in the collection process, and provision on request to the country for duplicate sets of the collected materials (Articles 8, 10 and 11). Separate obligations apply to sponsors ("see to degree possible collectors abide by Code," Article 12), curators (provision of further samples, Article 13) and users ("consider providing some form of compensation," Article 14).

This Code is seen as serving temporarily until national legislation is passed, or possible a legally binding international agreement like a protocol under the Biodiversity Convention is reached. A protocol is a separate agreement binding on those countries which adopt it. However, it and others of the type have the limitation of being strictly voluntary at this time.

B. Access Legislation

In this subsection, existing and pending access laws are summarized and evaluated for their expected effects on access and exchange. To date, only the Philippines and Queensland, Australia (to my knowledge) have laws in place. Several other countries/regions have progressed to the stage of a discussion draft, which are included here. But for the most part, countries are at the internal discussion level; this would include Brazil and Peru. Thus now is an appropriate time to consider approaches and consequences, before legislation is in place. On the other hand, the absence of legislation is reported to have a severe limiting effect on access, as in the case of India where some 9,000 medicinal plants have been barred from leaving the country (Jayaraman 1994). And the African Ministerial Conference on the Environment (AMCEN) has adopted a common position on the CBD, including a recommendation that African countries impose a

temporary ban on access to genetic resources until access legislation is in place. As this was a recommendation only, it is not immediately clear as to the degree of compliance.

Some suggestions have been made that the existence of the CBD language in an international treaty (the formal status of such agreements) is sufficient to establish national rights. However, under established legal interpretations, a sovereign right is distinct from a property right over individual resources (FAO 1995, App. 3). A national law is required to establish the individual property rights.

Philippines: The Presidential Executive Order No. 247, "The Prospecting of Biological and Genetic Resources", was adopted just one year ago (18 May 1995). Its status as an executive order, I have been told, means it is more easily modified than other forms of legislation. Hence it can be considered as provisional. Implementing rules and regulations are being drafted so there are no resultant agreements to report.

The Executive Order is somewhat complex with five main aspects:

- designate the administrative body (Inter-Agency Committee on Biological and Genetic Resources) (Sections 6 and 7),
- specify the need for either an Academic Research Agreement (Philippine research institutions only) or a Commercial Research Agreement (Section 3),
- specify disposition of samples (deposit full set in the Philippines; access by all Filipino citizens) (Section 4),
- particular rights for local and indigenous communities when within ancestral lands (prior informed consent of concerned communities obtained in accordance with customary laws) (Section 2), and
- provision for payment on identification of commercial use.

Points three and five should be scrutinized with some care, but it is the final that I find the most difficult.

The Philippines is a large country with a population of about 40 million, with many Filipinos living around the globe. Allowing any Filipino citizen rights to specimens and relevant data stored anywhere in the world is a lot to ask of a profit making firm. Some form of strict use control will certainly be needed. The notion of negotiating payment provisions prior to the identification of a commercializable product is a novel one. Typically it is an advantage to know the possibilities prior to the agreement, but the potential for subsequent adjustments could exist (at least to lower rates; the authority to require higher payments is not evident).

It is the mandate for prior informed consent from "concerned local communities" and regarding indigenous cultural communities, obtained "in accordance with the customary laws of the concerned community" that are problematic, in my view. For foreign firms, the identification of concerned communities and comprehension of customary laws is an open-ended requirement. How are concerned communities to be identified, and by whom. No firm would choose to make a sincere effort to comply with the law, yet risk at a later date having another community emerge to claim rights. Needed is either a careful definition of "concerned" or a body sanctioned to rule

that the identification of communities was complete. Let us hope these aspects are incorporated into the regulations. Otherwise I predict little commercial interest in Philippine genetic resources.

Queensland, Australia: Australia operates under a constitutional system granting significant rights to states. Hence its proclamation in the Nature Conservation Act of 1992 grants state ownership of wildlife in national parks, and conservation and resource parks, as well as all protected plants and animals, except plants occurring on private land. The State has authority to negotiate terms of access. Regrettably, a copy of those regulations has not been forthcoming so no details of the system used are available at this time.

Andean Pact: The Andean Pact nations (Venezuela, Columbia, Ecuador, Peru, and Bolivia) have a convoluted history as regards IPR. In the 1970s they adopted one of the more restrictive patent laws and regulations on foreign investment (McLeland and O'Toole 1987). This was subsequently modified along international lines only to have the ambivalence reemerge with the draft access legislation, "Regimen Comun Sobre Acceso a los Recursos Geneticos" (the Cartagena Agreement). The process itself has been tumultuous. A middle-of-the-road first draft developed in consultation with the IUCN Environmental Law Center was superseded by the current more extreme one partially under the advice of the Third World Network. National NGOs were extensively involved in the process as well. Some of the strains of the attempt for a harmonized approach are evident with national differences in indigenous rights and relationship with the private sector. Internally to the region, Columbia is said to have championed the version only, near ratification, to have apparent second thoughts, leaving the status of the draft in limbo for the present.

The draft legislation itself is quite complete and detailed, containing references to the CBD, to a regional administrative organization, and to a formal access application form. Implementation, as is standard with multinational agreements, requires the adoption of parallel national legislation. Here attention is on the access aspects only.

The permit process is a two-stage one, beginning with an application for access, under the auspices of a national Competent Authority. A detailed application form is included (Annex I) which requires information on:

- nationals who will participate,
- known and potential uses,
- assists to capacity building, and
- planned technology transfer.
- (a socioeconomic appraisal is optional under national law)

The Competent Authority then accepts or rejects the application following a site visit.

Accepted applications then proceed to the contract stage, also formalized by a form (Annex II). In addition to repeating much of the application information, would-be contractors must agree to certain rights and obligations, including prior information on research, and the provision of relevant information and publications. Accepted agreements, which are negotiated with the

State, are offered a contract. Applicants must also identify a scientific counterpart including a description of the counterpart's role. Royalties are the property of the state unless they or related information is from local, indigenous or African-American communities, in which case the State must share with those communities.

Apparently, much of this process is typical of the region, or at least Colombia, including state ownership of resources. Communities near oil producing areas frequently are granted lavish public facilities. But unlike oil, this system does not provide much incentive for private landowners to protect biodiversity. Indigenous, local and African-American communities have little control over their share of any benefits. Overall, it is rigid and complex, involving multiple parties and negotiations. It would seem similar results could be accomplished through a simpler system.

USA: Some express surprise that the U.S., which has yet to ratify the CBD, is included in a discussion of access legislation. Yet of course the CBD merely restated national sovereign rights for genetic resources; it did not create them in any way. The situation in the U.S. though remains as murky as elsewhere, but in one case the process has advanced. That instance applies to the U.S. Park Service decision to require commercialization clauses for research permits in Yellowstone Park (Milstein 1994). The hot springs there have yielded a number of heat-resistant microbes with industrial applications, many collected and marketed by foreign firms. Since 1994, firms must agree to negotiate a subsequent commercial use agreement for the granting of a research permit. To date, no commercial agreements have been established so terms and conditions remain unclear.

The immediate priority however is the determination of Park Service property rights to these organisms. Such property rights have evolved over time; presently, parks are considered owners of wildlife, but only when physically on park property. A study of the evolution of property rights through court decisions is presently underway which develops a strong case for the ownership of living materials in place in each park (Cahoon, personal communication). Either that approach, or the Queensland model of delineating ownership by legislative means, is needed in many countries.

C. Indigenous and Community Rights

One component of the issue of access to and use of genetic resources is that of rights of indigenous and local communities. These groups are associated with the preservation of and knowledge regarding genetic resources, yet are all too frequently omitted from benefits received. This has led to multiple calls for a new system of IPR specifically for what may be called indigenous inventions, roughly products derived from long term community observation and experimentation, such as herbal medicines and landraces. One indigenous group, the Indigenous-Tribal Peoples of the Tropical Forests, describes its expectations in clear terms, "we demand guaranteed rights to our intellectual property, and control over the development and manipulation of this knowledge.

To date, limited progress has been made on the development of a functional system for providing ownership and/or benefits. The Oxford Centre for the Environment, Ethics and Society (1996) has been the source of a proposed Traditional Resource Rights system, but one lacking "practical instruments" at this time. As described, it is a "bundle of rights", "covered under a significant number of international agreements that can be used to form the basis for a *sui generis* system." Yet the form of the *sui generis* system itself remains to be identified beyond the creation of an *"Ombudsman's Office"* to advise and represent indigenous groups. The proposed Rights system seems as much a process as a goal at present.

One earlier proposal (Gadgil and Devasia 1995) has been to enforce indigenous knowledge rights by requiring the owners of the source materials be identified in any resultant patents. This would necessitate agreement on any subsequent licensing arrangement. This approach alone would not suffice for protecting genetic resources for many products are never patented and if they are the patent may apply to a derivative compound suggested by the natural material, but not that specific material itself. This means ownership will often be unclear so the approach can be used only some of the time.

Swanson (1995) undertook an ambitious comparison of the role of IPR and "knowledge derived from the biological activities of natural organisms." In simple terms, he argues IPR protects informational investments (human capital) so that a parallel "informational resource right" could be established to protect "natural resource investments." In the former the industrialized countries are well endowed, the latter the developing economies, so there would be some rough parity. What the proposal overlooks in this comparative analysis is the requirement that patents protect only knowledge/information reduced to practice, i.e., functional inventions, not disembodied ideas. (The "utility" or "industrial application" requirement for patents; see section III.B above). Few natural organisms are anywhere close to marketable products. Protecting a "natural organism" therefore has no direct comparability with existing IPR systems, so that Swanson's initial 30 pages of analysis is often misdirected.

Operationally, Swanson's system would function through materials collected from "biodiversity reserves," the applicable form of natural resource investment for this system. "A state's programme would qualify for inclusion within the regime by means of investing in biodiversity reserves and establishing prospecting programmes." Discoveries there from "should be made subject to internationally-recognized exclusive rights on registration with some sort of centralized office (analogous to a patent office)." This registration office would determine the scope of the right based on the attributes of the genetic resource as well as the value and investment in the reserve from which it was collected. Other key administrative matters such as duration are left indeterminate. Clearly, these ideas do not apply directly to genetic resources and anyway are far from an operational system.

Stephenson (1994) similarly draws on an existing system as a model - in his case, computer software licenses. Sometimes referred to as "shrink wrap licenses", the text may specify that opening the package indicates an agreement to comply with the listed terms. Those terms are non-transferability and non-exclusivity, sometimes involving an annual fee. What is most

relevant to Stephenson is the broad similarities with traditional knowledge, especially its evolutionary nature (programs are frequently modified by suppliers and/or users). Yet the license is for a program in a fixed form (e.g., Word Perfect version 6.1a) with possible updates included. This is quite different from indigenous knowledge embodied in a form/product lacking in specific interest to Western markets so the analogy is, to me, not persuasive. Consider that many traditional societies are known to cover cuts with soil or other materials. That hints at the existence of antibacterial agents, but is a far cry from penicillin. One parallel which has been drawn on several occasions (e.g., UNDP 1994) is to blank recording tapes and other selected applications. There the very reasonable presumption is drawn that individuals will make copies, denying authors and artists royalties. The fund compensates those losses on some formalized basis; presumably the nationality and residence of the recipient would make no difference. While the concept is useful, indigenous knowledge lacks a universal media like recording tapes to which a fee can be attached.

Gollin (1993, p. 181) refers to a system of "discover's rights." These rights are operationalized through access legislation with the fee passed from the country "along to the person or group that discovered or traditionally used the species." That is, the proposal is for access legislation with sharing at the community level. The difficulty with that approach is the uncertain rights to genetic materials of many local and indigenous communities. Without recognition, it is difficult to consider a genetic resources property rights system based on ownership of the materials themselves, a situation akin to that of the U.S. Park Service.

My proposed solution (Lesser 1996) is the separation of ownership of the genetic resources from the ownership of the knowledge of its use. The complexity created is how to devise a workable system which protects disembodied knowledge without unduly hindering the sharing of information. My proposed **Reserved Rights** "reserves" local/indigenous rights by describing them in published form, such as a book on ethnobotanics or Bhatia and Kothari's (1996) Community Register system. In addition to the three standard clauses of an MTA described above, a Reserved Rights system would add:

- *for genetic materials listed in the **Registry of Traditional Uses** included in the Regulations for this legislation, a commercialization agreement must be negotiated with the community representative(s) identified therein.*

The Registry, which is proposed for inclusion in the regulations rather than the body of the law for the flexibility it provides, would incorporate the following information:
*Registry: The **Registry of Traditional Uses** shall consist of references to published listings of genetic resources uses for agricultural, medicinal, and other purposes. Listings shall include:*

1) *descriptions of use(s),to include all materials incorporated and any preparatory practices. Where there are multiple listings of the same genetic materials, the first published listing shall have priority,*
2) *scientific names, descriptions and/or photos of genetic resources employed in the above uses in sufficient detail such that the materials can be identified by knowledgeable individuals,*

3) *identification of community group representative(s) to be contacted for conducting commercialization negotiations, and*
4) *locally published, out of print or otherwise difficult-to-acquire listings shall be deposited in the National library and there made reasonably available, including a photostat service at prevailing government rates.*

D. CONCLUSIONS

Material Transfer Agreements, which have become commonplace in the sharing of genetic materials among researchers, contain the basic aspects of access legislation used at the national level. These are:

- research use only,
- no sharing with third parties without permission, and
- separate agreement required for commercialization.

As to existing national access legislation, the few examples in or near place (esp. Philippines, Andean Pact countries) are more elaborate due to the attempt to incorporate more aspects of transfer agreements, particularly:

- access for citizens,
- capacity building through value added activities in country, and
- systems for sharing benefits with local and indigenous communities.

While understandable and even desirable in many cases, the use of multipurpose legislation can make the outcome unduly complex and/or uncertain for users of those resources. "Indigenous knowledge" issues have been particularly problematic in this regard as knowledge is an intangible, difficult to protect without withholding that information altogether, which runs counter to the broad benefits from sharing knowledge.

My suggestion is to reserve the rights to knowledge by linking access legislation to knowledge revealed in printed form. That allows users to appraise before the exploration process who claims what ownership rights. More broadly, in my opinion, access legislation needs to be relatively simple with limited objectives. If required, additional laws, each narrow and specific, may be used for additional purposes. Simpler legislation is also likely to be adopted more readily, for in the current void there is the real threat that countries, following the AMCEN resolution and India, will prohibit the exportation of generic resources, and we shall be the poorer for that. One final suggestion is that researchers become actively involved in the drafting of these laws. The legislation will directly affect your work; your input into the systems is therefore essential if it is to be done properly the first time.

IV. MULTILATERAL SYSTEMS: AGRICULTURAL GENETIC RESOURCES

Bilateral systems of the type described above are considered ill suited for agricultural and food resources for several reasons. The resources are unevenly distributed worldwide, necessitating

exchange. Certainly we in North America are well aware of our past debt to other regions for our foodstuffs and ongoing need for genetic materials. There is basic compassion, for we all require food. But we require medicines as well, and no similar arguments are put forth. Then there is the experience of the International Agricultural Research Centers (IARC) which, despite some oft-identified problems, have provided for basic human welfare. Those Centers depended on ready access to genetic materials for their work. But perhaps most pertinent (at least to an economist) is the realization that most agricultural genetic resources have little market value. And what value exists will be difficult to distinguish from the other components of the complex genetic make up of commercial varieties. This means that exchange systems cannot become too complex (the number of possible bilateral agreements is staggering) for then the transaction costs reduce gross benefits, meaning less is done. Overall it is widely accepted that open access to agricultural genetic resources be maintained. Free access - nonpaying access - though is a thing of the past. How then to permit open access while sharing benefits?

Complicating the matter still further is the distinction made in the CBD between materials collected before and after the Convention went into force. In particular, the Convention requirements apply to those materials "acquired . . . in accordance with this Convention" (Article 15(3)). This technically leaves the bulk of *ex situ* collections, including the extensive holdings of the IARC, beyond the scope of the Convention. Practically of course they are linked in peoples' minds, especially so in supplier countries where there have been complaints for years about the "common heritage" approach to genetic resources. For many, this means the basic resources are unpriced while "improved" materials are sold. Indeed, Resolution 3 of the Nairobi Final Act, a kind of appendix to the CBD, states, "Further recognizes the need to seek solutions to outstanding matters concerning plant genetic resources . . ., in particular: (a) Access to *ex-situ* collections [acquired before the CBD enters into force]; and (b) The question of Farmers' Rights." Here I shall explore the current status of Farmers' Rights and proposals by FAO for a multilateral access system.

A. Farmers' Rights

Farmers' Rights is the term developed by the FAO under the so-called Revised Undertaking for Plant Genetic Resources. While not necessarily restricted to plants with agricultural applications, it is quite evident that is the intended focus of the Undertaking. In Resolution 5/89 Farmers' Rights are defined as "rights arising from the past, present and future contributions of farmers in conserving, improving and making available plant genetic resources . . ." Farmers' Rights are to be "implemented through an international fund on plant genetic resources which will support plant genetic conservation and utilization programmes, particularly, but not exclusively, in the developing countries." (FAO Resolution 3/91, Annex 3 to the International Undertaking). No further details on the implementation and operation of this Fund are included.

In concept, Farmers' Rights operate more as a moral obligation than an economic incentive. They are not connected with any specific future action but rather with a general conservation and equity objective. This is noted without prejudice but only to emphasize that the objectives, and hence the likely results, of the system are quite different from IPR.

Perhaps the major comment which can be made is the lack of action on the Fund since its proposal. The time span has been relatively short, but there are few indications to date that such a Fund will be constructed, at least under these specific auspices. The entire International Undertaking process received much negative attention in the developed countries early on due to the interpretation of "plant genetic resources" to refer to both unimproved and improved genetic materials (Article 5) (see Grossman 1988). Private firms have not made their products available without charge, and while it is a matter of interpretation if that was specifically required by the Undertaking, it did poison the atmosphere. Subsequently, the proposed tax on seed sales was never supported.

The Undertaking is scheduled to be renegotiated in September so possibly some useful approaches will be identified. My personal suggestion is, at a minimum, the terminology of "Farmers' Rights" should be abandoned as it has become too emotion-charged. The opportunity for a calm discussion of this important concept under that title seems to have passed. Perhaps using a dispassionate title like "Plant Genetic Resources Foundation" would advance the process, at least a little.

B. Proposed Multilateral System

The FAO Commission on Plant Genetic Resources has proposed itself as the responsible agent for agricultural genetic resources under the CBD and, as an aspect, commissioned the International Plant Genetic Resources Institute (IPGRI) to propose options for exchange and benefit sharing. (Pistorius 1995 provides a background discussion; this proposal is part of the FAO Global Plan of Action, aspects of which will be discussed at the Leipzig meeting in June). The information provided here is from a February 2 draft summary, all that was made available to the public. A reading of the full text or any subsequent updates could have led to different conclusions.

While a number of options are highlighted, the bulk of the attention is directed to a multilateral system titled MUSE (MUltilateral System for Exchange). The report is rather lengthy, but the outlines of MUSE can be set down succinctly, as follows:

Voluntary: The system is to be voluntary, open to all. This means there will be **members** and **nonmembers.** Members may be countries, institutions, communities, and individuals. Members would contribute as able, including materials, information and/or funds.

Agreement: Membership is secured through the signing of an Agreement indicating willingness to abide by standard, mutually agreeable terms (**MAT**) and standard terms of prior informed consent (**PIC**). A separate set of standard terms would be developed for nonmembers.

Compensation: The establishment of a compensation fund is considered, possibly as a component of Farmers' Rights. In addition to generating funds, provisions are needed for their allocation. Along with this multilateral compensation system, members have the right to enter into **bilateral negotiations**, especially for commercial commodities (e.g., rubber).

Scope: Included range of genetic materials is to be determined; recommended to be as broad as feasible, including both *in* and *ex situ* materials, and possibly before as well as after the entry into force of the CBD.

Governance: The Agreement is to be administered under the CBD by an intergovernmental organization to be identified.

In short, this MUSE system proposal is for a standardized MTA agreed to beforehand. In that regard, it has a parallel with patents which too can be considered a standardized, multilateral contract specifying rights and obligations. The MUSE provides equity in the form of standardized treatment, and enhances access by providing for a system open to all. Beyond those few generalities it is difficult to comment because what has been proposed (at least in the summary) is a broad outline of a system, nothing close to an operational one. Due to the lack of details, it will be equally difficult for potential members to present views as it is not clear just what will be judged. It appears there might be a fund, but the size and management would be key considerations for many members (as would any expected contributions from others).

If the drafting committee is seeking endorsements, they have mine as well as my commendation for bringing the process this far. What is required now - urgently in my mind - is to move to the next level of specificity. If resources are to be spent in discussing this proposal, it is the specifics we need now to get before us. My suggestions are as follows:

Governance: The suggestion for an intergovernmental administrative organization is cumbersome and likely unnecessary. The basic Agreement can be developed under the auspices of the CBD, then adopted into national law (the general pattern for international conventions).

Access Legislation: National access legislation could be drafted to specify which forms/sources of genetic resources could be accessed on multilateral terms; the option would always remain to select bilateral negotiations. This is not different from the scope requirements of MUSE. I would propose that included materials previously covered by another access system, such as the CGIAR/FAO genebanks, not be included.

Multilateral Compensation System: This is a basic issue, for without a compensation plan for the open access system, nothing really has changed from the present. That would be widely unacceptable to supplier countries, as payments into a general fund have been unacceptable for industrialized user nations. One approach would be to establish a new medium of exchange, "Genetic Materials Chits". A basic price system would have to be established, so many Chits for wild relatives, landraces, improved and characterizes, etc. (Prices could be equal; periodic revaluations would be expected during the early period). Countries which exactly balanced outgoing with incoming materials would come out neutral; others would have a surplus or deficit. A market (possibly automated on the World Wide Web) would be available for selling and buying Chits, giving net sellers some income. Materials so acquired could not be resold to third parties (exceptions may be allowed in rare circumstances). Nonpriced transfers such as for backups for genebank holdings could continue unaffected.

The problem remains of compensation for unusual materials which after the initial transfer are found to have significant value. Consider for example wheat dwarfing genes, now present in a large portion of the world wheat crop. To allow for such admittedly rare but nonetheless visible cases, the agreement could specify a small royalty (say 1%) be paid to the supplier country or institution for seed sales above some significant level (say US$ .5 million), provided the seed is protected by PBR or other mechanism. Without the protection mechanism, competing firms could propagate the seed and sell it with no requirement for paying the special royalty (they would not be bound by the original access agreement). There would also need to be a "clearly evident" relationship between the acquired genetic materials and the valuable trait. Recall, the intent is to provide for only unusual events, not to provide a general royalty scheme, which would quickly become unwieldy.

Resolution of Conflicts: A number of commentators on the general subject of IPR have correctly noted that the resolution of disputes in court is extremely costly, creating in itself a source of inequity. For any multilateral system, I would suggest the Agreement specify binding arbitration (meaning no appeal to the courts; the New York Convention specifies that signatory countries agree to abide by the binding aspect of the agreements). Arbitration is faster and less costly than litigation, and, staffed by practitioners, has the advantage of involving knowledgeable individuals. There are a number of patterns available for modeling an arbitration process, note for example the American Arbitration Association or, for IPR, the World Intellectual Property Organization Arbitration Center (WIPO 1993).

C. Conclusions

The appropriate and acceptable means of transferring agricultural genetic resources is a particularly complex yet important one. The long-prevailing "common heritage" system worked extraordinarily well for research access, but did little directly for the supplier countries. That system is rapidly coming to an end. Prior attempts for creating a general compensation fund - particular reference is made in that regard to Farmers' Rights - has never really progressed. At minimum I suggest a name change to something like "Plant Genetic Resources Foundation" or a similarly neutral term.

Most recently, FAO through its Commission on Plant Genetic Resources has proposed the outlines for a multilateral exchange system. Arguments for the multilateral approach are persuasive, but the proposed Agreement lacks all but the most basic details. Particularly absent (at least from the summary available to me) is a real formulation of the compensation system. And without general compensation, it is difficult to see that much progress has been made. This proposal, in my assessment, requires immediate attention to the next level of operational details. One suggestion I can offer is a consideration of a new monetary system ("Chits") for the materials. Materials are valued in Chits; real payment comes when Chits are sold to buyers, the users of the materials. This would provide for an ongoing market assessment of the commercial worth of genetic resources. Special arrangements can be made for the rare instances when materials, unrecognized from the start, prove to have exceptional value. All these concepts can be incorporated into national access legislation, minimizing the need for a major oversight organization.

V. CONCLUSIONS

Much of the ongoing discussions concerning access to genetic resources is motivated by the "sovereign rights" and "equitable sharing" clauses of the CBD. What seems to have been largely overlooked is the concomitant requirement (Article 15(2)) to "facilitate access . . . and not to impose restrictions that run counter to the objectives of this Convention." Aspects of current access legislation would, in my judgment, "impose restrictions." The basic issue for me regarding that legislation is twofold, it attempts to exert too much control and serve multiple purposes with a single piece of legislation, making it unwieldy. Underlying this is a perceptions failure.

A market failure occurs when markets do not value/price products; the existence of pollution is a market failure, for producers do not pay for the damage caused. The low price accorded genetic resources is not a market failure for, individually, they actually have a low current value. It is a perceptions failure for suppliers see the aggregate historical value (which is immense) and project that into a future unit value. That has some parallels with predicting the coin toss of a "head" following four successive tosses of "tails." We know that tosses are independent, yet treat independent events as if they were sequential. In a like manner, we know over time germ plasm has been valuable, and certain individual parts will be valuable, and project a high overall expectation. Consider also lottery tickets. An individual ticket may be worth $10 million, but the average ticket has a very low value. With genetic resources, attention is focused on the "winners," not the average.

In establishing a rational system, we must accept that individual genetic resources have a low current value. This does not say owners/providers should not be paid. Payment is required for both equity and conservation incentive purposes. What it does say is that exchange systems must be simple or the transactions costs will consume what value there is. Probably the Farmers' Rights approach is the best one socially, but its operationality is highly questionable. Another multilateral system would be the second choice; the problem though remains the same, how to generate a payment stream which is acceptable to suppliers. In that regard, the proposed MUSE system is found wanting. I have offered a suggestion, but its functionality is in doubt. This is a key issue which warrants input from a larger group.

Thus what remains is access legislation/MTAs. There has been talk of a *sui generis* system, but such systems operate on the basis of (1) identifying a probable use for protected materials, and (2) reasonable probability of use. U.S. patents are commercialized at only something like a 15 percent rate. The probability of finding a medicinal product through random screening is approximately 1/10,000. Clearly, it is not feasible to protect a mass of materials with the expectation of payments when the vast number will never be utilized commercially (although it may have other important uses). Attempting to do so would be enormously expensive plus causing serious damage to research access. What we need then is a model for an international MTA. Current models as I have indicated are wanting. The scientific community could assist by stepping forward to publicize their experiences with MTAs. Much of importance rides on the identification and widespread adoption of appropriate access legislation. Yet perhaps the worst

scenario is one of few operational national systems. That will lead to national bans on exchanging genetic resources and, when materials are somehow acquired, questionable use rights.

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