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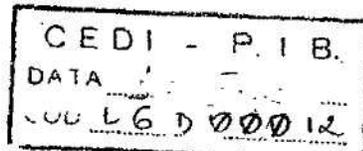
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THIRD WORLD NETWORK DISCUSSION PAPER

TOWARDS A LEGAL FRAMEWORK FOR PROTECTING BIOLOGICAL DIVERSITY
AND COMMUNITY INTELLECTUAL RIGHTS - A THIRD WORLD PERSPECTIVE

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TOWARDS A LEGAL FRAMEWORK FOR PROTECTING BIOLOGICAL DIVERSITY
AND COMMUNITY INTELLECTUAL RIGHTS - A THIRD WORLD PERSPECTIVE

Gurdial Singh Nijar

I. The Link Between Peoples' Knowledge Systems and Protection
of Biodiversity

Throughout history, biodiversity has been the commons of local communities with both resources and knowledge being freely exchanged. Diverse and viable knowledge systems developed based on the life-support capacities of the Earth's bounty. There was a symbiotic relationship: people lived off nature even as they helped sustain it. The life of communities was enhanced, spiritually, culturally and economically even as the communities enhanced earth's biodiversity.

The knowledge and practice relating to forestry and agriculture best illustrates this. In local knowledge systems, the plant world is not artificially separated on the basis of separate commodity markets to which they supply raw materials and resources: forest supplying commercial timber and agricultural land supplying food commodities. Instead the forest and the field are in ecological continuum. Activities in the forest contribute to the food needs of the local community, while agriculture itself is modelled on the ecology of the tropical forest. Some forest dwellers gather food directly from the forest while many communities practise agriculture outside the forest, but depend on the fertility of the forest for the fertility of agricultural land. (1)

The life-support, food-giving capacities of the forests have spawned the local knowledge systems. This has led to the development of knowledge, practices and lifestyles designed to preserve the integrity and diversity of the forest and its sustainable use. Such knowledge has been steadily eclipsed and marginalised, largely by colonialism and the ensuing industrialism of the West. The diverse knowledge systems that developed with the diverse uses of the forest for food and agriculture were ignored, and substituted with a monoculturalised view that valued the forest only in terms of its industrial and commercial timber resource. Thus ignored by this forestry science is, for example, the knowledge of the Hanunoo in the Philippines of 1,600 plant categories; of the Lua Tribe in Thailand of cropping systems based on 160 crops; ignored as well is the life sustaining food system based on the forest for the Kayan, Kenyah, Punan Bah and Penans of Sarawak. They rely on, for example, fungi (23 varieties eaten by Kenyah and 43 by Iban), and sago, which is the starch derived from the pith of a palm tree.

In South India, the Soliga tribe from the Belirangan hills of Karnataka uses 27 different varieties of leafy vegetables and a variety of tubers, leaves, fruits and roots for medicinal purposes. The staple diet of the tribes in Madhya Pradesh of rice and lesser millet is complemented with seeds, grains, roots,

rhizomes, leaves and fruits of some 165 trees, shrubs and climbers of the forest.

In non-tribal areas too forests provide food and livelihood through critical inputs, to agriculture through soil and water conservation; of fodder and organic fertiliser. Indigenous silvicultural practices are based on sustainable and renewable maximisation of all the diverse forms and functions of forests and trees. This knowledge passed through generations assures the survival of the forest, its component parts, its sustainability and the people and cultures dependent upon it and the ecosystem as a whole.

Defining the value of forests in terms only of its source as commercially exploitable timber reduces the value of diversity of life in the forest to the value of a few commercially valuable species, and further, to the value of their dead product. This reductionism is destructive of the integrity of the forests and, as well, of forest cultures which tap the forests in its diversity for their food, medicine, fibre and shelter.

Diversity gives way to uniformity - even-aged single species stand; so too in agriculture, only species whose production can be optimised for commercial interests are advanced. The genetic base of commercial agriculture becomes extremely narrow. The isolation of characteristics which are 'beneficial' further results in reduction of genetic variety. The Green Revolution high-response varieties of wheat and rice displaced traditional crops, creating vast areas of monoculture.

Biotechnology in crops expedites this tendency towards monoculture as biotechnologically-developed crops replace locally adapted strains or the advantages of local planting techniques which are geared towards maintaining diversity rather than productivity. The economic impetus of biotechnology slowly causes a further erosion of the world's biological diversity propelling agriculture production towards greater uniformity.

Similarly the homogenisation of livestock populations is resulting in the irreparable loss of diversity. The cross-breeds of Jersey and Holstein cows are replacing the carefully evolved pure breeds of cattle such as the Sahiwal, Red Sindhi, Rathi, Tharparkar, Haryana, Ongole, Kankreji and Gir. The animal disappears from the farming system and the organic fertiliser is substituted by the chemical. The soil, fauna and flora also become extinct.

The locally specific nitrogen-fixing bacteria, fungi that facilitate nutrient intake through mycorrhizal association, predators of pests, pollinators and seed dispersers, and other species that co-evolved over centuries to provide environmental services to traditional agrosystems have become extinct, or have had their genetic base increasingly narrowed. Soil microbes, deprived of the flora with which they have co-evolved, also disappear. (2)

Biodiversity erosion thus starts a chain reaction which ultimately threatens the life-support systems and consequently the livelihoods of the teeming millions of the Third World dependent and co-existing with it.

In addition, of course, there is growing appreciation of the value of the knowledge and experience of local and indigenous communities in the use of the medicinal, agricultural and other useful properties of endemic flora and fauna. Between 300,000 and 750,000 plant species are thought to exist in the world with much of the diversity found in tropical zones. While fewer than 1% of this diversity has been documented by science for their medical or chemical properties, valuable information about these resources is contained within culturally diverse knowledge systems. (3)

Traditional remedies, although based on natural products are not found in "nature" as such; they are products of human knowledge. To transform a plant into a medicine, one has to know the correct species, its location, the proper time of collection (some plants are poisonous in certain seasons), the part to be used, how to prepare it (fresh, dried, cut in small pieces, smashed), the solvent to be used (cold, warm or boiling water; alcohol, the addition of salt, etc.), the way to prepare it (time and conditions to be left in the solvent), and, finally, posology (route of administration, dosage). (4)

It is estimated that three quarters of the plants that provide active ingredients for prescription drugs came to the attention of researchers because of their use in traditional medicine. (5) Of the 120 active compounds currently isolated from the higher plants and widely used in medicine today, 74% show a positive correlation between their modern therapeutic use and the traditional use of the plant from which they were derived for. (6)

Michael Balick of the New York Botanical Gardens found that using traditional knowledge increased the efficiency of screening plants for medical properties by more than 400%. (7) The current value of the world market for medicinal plants derived from leads given by indigenous and local communities is estimated to be US\$43 billion. (8) Furthermore, the value of crop varieties improved and developed by traditional farmers to the international seed industry is estimated to be US\$15 billion. (9) In addition to medicines and agricultural products, other natural products developed by indigenous peoples and local communities such as sweeteners, perfumes, fabrics and cosmetics, are in everyday use. With a growing market for natural products the value of these contributions will continue to rise. (10)

The link between such knowledge and practices of local peoples, in short their conservation ethic and understanding, and the preservation of biodiversity is of crucial importance.

II. International Developments Affecting the Recognition of Rights in Biodiversity of Nations, Farmers and Indigenous Peoples.

a) UPOV, FAO and Farmers' Rights

Throughout history, biodiversity has been the commons of local communities with both resources and knowledge being freely exchanged. No concept of sovereign rights of resources or property rights in genetic resources existed. What contributed to the emergence of property rights for commercial benefits in this area was the enactment in the early 1960s of an International Convention - the Union for the Protection of New Varieties of Plant (UPOV). The South wherein the biodiversity was concentrated, was tapped freely for source material, farmers' germplasm, on the rationale that it formed the common heritage of mankind. Corporate interests, predominantly from the North, invaded the local commons for free, made "improvements" in the breeding process by modifying the plant variety's characteristics and quality, and claimed property rights on the same basis as a claim for a patent of an invention of an industrial product (i.e. novelty, industrial application and originality).

The innovative contribution and knowledge of local communities to the evolution of the seeds concerned were ignored. No reward existed for them. This inequitable treatment between owners of germplasm and owners of technology spawned a debate in the FAO in the 1970s. Developing countries complained that "the common heritage of mankind" taken from within their borders for free was now returned as a commodity at a price. As a response, the FAO at its 22nd session in 1983 adopted an Undertaking. (For status of the Undertaking and CPGR and FAO Global System, see Appendix 1).

The Undertaking recognised free access to basic source material as well as to improved and elite varieties. Several industrialised countries rejected this Undertaking arguing that improved materials did not form part of the common heritage of mankind. In the March 1987 meeting of FAO's Commission on Plant Genetic Resources, the South asserted that farmers' rights were founded on the basis of their having domesticated their important agricultural crops, and observed, developed and safeguarded the tremendous biodiversity that breeders and the seed industry use as their source material. Innovation was thus an integral part of farmers' breeding of their seed varieties. These debates finally led to the international recognition of both Plant Breeders' and Farmers' Rights in 1989.(11) This recognition is expressed in resolutions 4/89, 5/89, and 3/91, which were negotiated by the Commission on Plant Genetic Resources and unanimously approved by more than 160 countries in the FAO Conference in 1989 and 1991.

Farmers' Rights was a recognition of "the enormous contribution that farmers of all regions have made to the conservation and development of plant genetic resources" (Resolution 4/89).

Farmers' Rights were defined 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 were declared by this resolution to be 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.

FAO envisages that the implementation of these rights would ensure that farmers, farming communities and their countries, receive a just share of the benefits derived from plant genetic resources which they have developed, maintained and made available. It thus sees Farmers' Rights not only as a matter of justice and equity, but by providing incentives and means for the conservation and further development of these plant genetic resources by farmers, a question of "ensuring that the genetic resources on which we all depend are conserved and continue to be made available." [FAO, Progress Report on Resolution 3 of the Nairobi Final Act: Ex Situ Collections and Farmers' Rights (1994)]

The contribution of the traditional farmer in developing the plant was acknowledged. But the right was not vested in the individual farmer. Instead it accrued to the farmers' governments to receive assistance in the maintenance of genetic resources. It is essentially a general obligation of the North to help the South, tied into the context of aid and dependency.

An international gene fund, administered by FAO for the conservation and utilisation of plant genetic resources was set up to concretise these "farmers' rights". However, the lack of contributions from Northern corporations and their governments rendered this fund inoperative.

The debate did not end there. This was because of (a) the extension of patent rights to genetic materials, and, (b) the growing importance of biotechnology. In addition to the conflicts between agribusiness and farmers' rights, pharmaceutical companies were also enjoying free access to genetic materials from the forest (especially tropical rainforests), and tapping the vast knowledge of forest peoples, again for free.

The viability of FAO's 1989 Undertaking itself came into question because of several developments in international negotiations. These were: (a) the revision of the UPOV Convention, (b) Trade-related Intellectual Property Rights Agreement negotiations in the Uruguay Round of GATT (TRIPs), and, (c) the Biodiversity Convention.

The first two substantially broadened the gap between source materials and improved varieties in terms of value and ownership rights attached to them. The rights of breeders/inventors over improved varieties are given greater recognition at the expense of rights of local communities over source materials which

themselves are the results of innovation and improvements by generations of farmers.

b) 1991 UPOV Revision

The 1991 Revision of UPOV further restricted the farmers' rights. The protected variety may still be used as an initial source of variation for the creation of new varieties but such new varieties cannot be marketed or sold without the plant breeders' rights (PBR) holder allowing it. As the PBR holder will want to maximise his sales and profit, his authorization will almost certainly not be given. Breeders' rights have also been extended to cover not only production for sale, but also for reproduction, multiplication, conditioning for the purpose of propagation, and exporting/importing and stocking for these purposes.

Governments have the option to adopt in their national law the right of the farmer to use his seed for replanting. It is unlikely, however, that developing countries will do so. They are under extreme pressure from the Northern countries to harmonise their legislation with the IPRs standards promoted by the North. So if the United States or the European Community do not make use of this option, the developing countries will also be excluded from authorising their farmers to re-use their own seeds. Yet another restriction is that harvested material cannot be sold or marketed without the breeders' authorization. If royalties are not paid, the breeder can interpose to prevent the farmer from selling the produce. These changes have made PBRs seem to offer the same kind of iron-clad protection as do patents.

c) TRIPs in GATT

Article 27(3)(b) of the TRIPs Provision of the GATT Final Act obliges Members to provide for the protection of plant varieties. This they may do either by patents or an effective sui generis system or any combination of these. The only such system available now is that under UPOV which favours plant breeders. Each country is, of course, free to set up its own system. (This is explored later).

Members may exclude from patentability plants and animals which are not considered to be technologically improved varieties. Again a distinction is drawn between genetic material developed in the North by technologists and that which has been developed in the South by farmers or indigenous populations. Essentially, this is a clash of definitions of knowledge systems. TRIPs recognises only the Northern industrialised model of innovation and has failed to recognise the more informal, communal system of innovation through which Southern farmers produce, select, improve and breed a diversity of crop and livestock varieties. This collective intellectual property of Southern farmers is denied recognition, and hence protection.

For traditional societies, biodiversity is common property, and knowledge related to it is the intellectual commons. For biotechnology corporations, biodiversity becomes private property

through their investments, and TRIPs are the means for such privatisation. Additionally, IPRs are only recognised when knowledge and innovation generates profits, not when it meets social needs. Article 27(1) makes clear that to qualify for patenting, an innovation must be capable of "industrial application". Further the fact that IPRs must be trade-related to be recognised, TRIPs in GATT will finally lead to an extension of the monopoly rights of multinational corporations over production and distribution. At the same time, innovation in the public domain which is mostly for domestic, local and public use will rapidly be undermined and the related institutions dismantled. This will deepen the North-South rift with the ensuing unfair and unequal exchange. Millions of farmers in the South will be forced to buy patented seeds which originate in the South. This will discourage the continuation of seed diversity and create high-priced dependency by farmers. Similarly, consumers will have to pay exorbitant prices for pharmaceutical drugs developed from genetic material and often, -from the knowledge of indigenous forest communities of the South.

d) The Convention on Biological Diversity (12)

The impetus for the Convention came from Northern conservation groups and the biotechnology industry, one to protect disappearing tropical forests and the other to ensure biological capital for the generation of profits. The South which holds most of the biological resources and diversity of the world argued that free access and IPR protection for the North created an unequal and unfair exchange. In this context the Southern governments looked forward to an international recognition of their ownership rights in genetic resources; and accessing advanced technologies of the North (especially biotechnology) in exchange for granting access to their genetic resources to Northern enterprises. For this reason the Biodiversity Convention was important for Southern countries.

The Convention recognised that States have sovereign rights over their natural resources. They determine access to their genetic resources. It is subject to their national legislation. Thus the "common heritage principle" is abandoned in favour of "sovereignty over natural resources." The State thus regulates access and can deny it if it be inimical to its national interest.

Secondly, the Convention obliges States to endeavour to "create conditions to facilitate access for environmentally sound uses" by other States and not to impose restrictions that run counter to the Convention's objectives. Its objectives are declared to be:

- (i) conservation of biological diversity;
- (ii) the sustainable use of its components;
- (iii) the fair and equitable sharing of the benefits arising out of the utilisation of genetic resources (Article 1).

As authority to determine access rests with the State, it is the

State's legislation which will determine what constitutes "environmentally sound uses".

Thirdly, the Convention stipulates conditions (in addition to those set out by national legislation) for the grant of access to its genetic resources. Thus access shall be

- (i) on mutually agreed terms, (Article 15.4),
and,
- (ii) subject to prior informed consent of the State of the resource. (Article 15.5)

An important limitation is established by the Convention. It is to apply only to in situ and ex situ resources acquired in accordance with the Convention, but not those taken away and deposited in gene-banks prior to the Convention. This is of special significance because most existing international collections are under the control of the North. Of the 127 base collections of the International Board of Plant Genetic Resources (IBPGR), 81 are in the industrialised countries and 29 are in the CGIAR system which is controlled by the governments and corporations of the industrialised countries in the North. Only 17 are in the national collections of Southern countries.

The Convention expressly recognises that both access to and transfer of technology are essential elements for attaining its objectives.

Each party undertakes to provide and/or facilitate access for and transfer to others technologies that

- (i) are relevant to the conservation and sustainable use of biological diversity, or,
- (ii) make use of genetic resources and do not cause damage to the environment (Article 16.1)

This access to and transfer of technology is to be provided to developing countries under fair and most favourable terms, including concessional and preferential terms. These terms, however, will only apply

- (i) where mutually agreed, and,
- (ii) where necessary in accordance with the financial mechanisms set up by Articles 20 and 21 of the Convention.

This almost certainly suggests that such concessional and preferential terms will hardly ever be applied. The Article goes on to draw a distinction between patented and non-patented technology. In the case of the former the terms on which access and transfer is provided shall be consistent with "the adequate and effective protection of intellectual property rights" (Article 16.2). This would appear to refer to the standards set out in the TRIPs which, as we have noted are the stringent IPR standards of the North which are unacceptable on the grounds discussed above.

With regard to technologies which make use of genetic resources, the Convention obliges States to take legislative, administrative or policy measures to give access to and transfer of technology

on mutually agreed terms to other States, especially the developing countries which provide the genetic resources. The technologies include those that are protected by patents and other intellectual property rights. (Article 16.3)

The Convention also obliges States to take legislative or policy measures to ensure that the private sector facilitates access to, joint development and transfer of technology to governmental institutions and the private sector of developing countries. This is to be done in accordance with the obligations set out in the earlier paragraphs 1, 2 and 3 of paragraph 16. (Article 16.4). These are, as noted earlier, not set out with any specificity.

The whole of this Article 16 on the transfer of technology and IPRs is far from clear. It is therefore open to interpretation and definition.

The Convention calls upon contracting Parties to ensure that such IPRs are supportive of and do not run counter to its objectives. In view of recent trends to oblige developing countries to strengthen intellectual property rights protection, the Convention may offer an opportunity to reject the establishment of a regime which will be incompatible with its objectives.

The Convention recognises the role of indigenous and local communities in conserving and sustainably using biological diversity, states that the benefits arising from their knowledge and innovation should be equitably shared and urges States to initiate methods for the development and use of indigenous and traditional technologies in pursuance of conserving and using biological diversity. It further exhorts Parties to protect and encourage customary use of biological resources in accordance with traditional cultural practices that are compatible with conservation or sustainable use requirements.

What emerges from a review of these international developments and debates is that there is an acknowledgement that farmers' and indigenous peoples' rights are essential for the conservation and protection of biological diversity and that this emanates from a recognition of their diverse systems of knowledge and innovation in biological resource improvement and utilisation; and that equity demands a sharing of benefits. However, what emerges equally clearly is that the existing international mechanisms are not entirely supportive of this understanding. The search for a coherent legal framework advancing this understanding is therefore of crucial importance for the preservation and protection of these critical values.

III. Search for a Legal Framework for Regulating Access.

Article 15 of the Convention on Biological Diversity recognises that States have sovereign rights over their natural resources. They determine access to these genetic resources and their national legislation will prevail.

This clear recognition will undoubtedly prompt States to amend, modify or even promulgate national legislation to regulate access to such resources. The terms and conditions for the grant of access are entirely within the domain of national legislation. The Australian State of Queensland, for example, has proposed an amendment to its Nature Conservation Act "to give the State outright ownership of its flora and fauna and guarantee that it shares in any profits made from exploiting them", an action it sees as essential to "halt a systematic search of our biota by foreign laboratories and pharmaceutical companies".

Often there is no single coherent legislation to govern access in most countries. Instead it is spread in a diaspora of legislation over different sectors of the bureaucracy. This often makes regulation and management difficult, uncoordinated and cumbersome. A typical example is Malaysia where much of the legislation is sector-based: fisheries resources by the Fisheries Act 1985, wildlife by the Wild Life Act 1972, forests by the National Forestry Act 1984 (Amended 1993). There is no single authority to legislate for matters relevant to biological diversity because of the federal structure of Government and the distribution of jurisdiction to legislate between the Federal (central) authority and the respective States. Some matters can be dealt with by both the State and Federal authorities, such as the protection of wild animals and wild birds, and National Parks. Forest and agriculture fall exclusively within the legislative authority of the State. The Malaysian National Committee on Plant Genetic Resources in its draft of the National Policy on Biological Diversity noted the serious deficiencies as: an absence of integrative approach across the sector, due to the limited scope of various enactments in relation to biological diversity conservation; a lack of comprehensive coverage of biological diversity issues; and, finally, the constitutional distribution of legislative process between the State and the Federal Governments that result in areas of over-lap and non-implementation between States.

These problems are endemic to many Third World countries, and exacerbated in a federal-type Constitution.

A suggested alternative would be to enact a single legislation covering all the sectors which each State then adopts formally as part of its State legislation in respect of matters over which it has exclusive jurisdiction. This was done, for example in Malaysia, in setting up a single legislation, the National Land Code, to govern matters pertaining to land, which is the preserve of State legislatures. Uniformity is particularly critical in legislation designed to protect a nation's biological diversity as the same flora and fauna will invariably exist across State

boundaries.

a) Licensing of Collectors

Sovereign rights in resources accords the right to regulate access. Indeed Article 15.2 obliges the parties to facilitate access to genetic resources for environmentally sound uses and not to impose restrictions that run counter to the objectives of the Convention. Access is made subject to prior informed consent of the contracting party providing such resource unless otherwise determined by that party. (Article 15.5). Access has to be on "mutually agreed terms". (Article 15.4).

The cumulative effect of these provisions appears clearly to be

- (a) the State may set up legislation regulating access.
- (b) considerations regulating access can also include
 - (i) a denial of access if it is inimical to its national interest.
 - (ii) predicating access for "environmentally sound uses", a term which will need to be defined.
 - (iii) Access on mutually agreed terms should include the right of the State to participate in research and development activities (Article 15.6), and, the right to share in a fair and equitable way the benefits arising from their commercial and other utilizations (Article 15.7).

The use of the expression "mutually agreed terms" seems to suggest an *ad hoc* contractual arrangement. But this does not necessarily preclude the enactment of legislation which incorporates the minimum terms and conditions set out in the Convention and furthering its objectives. Such kind of legislation is often promulgated to ensure the orderly development and management of an activity, and to protect a particular class of people, often a weaker party. On this basis countries have enacted Acts relating to Employment (to stipulate minimum terms and conditions of employment), Hire Purchase (to regulate the commercial hire purchase of consumer goods) the Sale of Goods (dealing generally with express and implied terms relating to the sale of goods) and Housing Development (to control and regulate housing developers as well as the contents of Sales and Purchase agreements between developers and consumers). [See Appendix 2 for Draft Model of Collectors of Biological Resources (Control and Licensing) Act]. Licensing laws often also exist to regulate the conduct and activity of certain categories of entrepreneurs on the rationale that their activity impacts on the public. (See Appendix 3 for Draft Model Contract between the Collector and the Government Parties).

The protection of biological diversity is particularly amenable to such legislation. Its importance has been underlined. If allowed *ad hoc* private contractual arrangements much would depend on the strength of the respective negotiating parties, in this case between industry (often transnational corporations) and a Third World State with the biodiversity. Experience has shown that TNCs are more able to assert their terms and with a strong IPR regime favouring industry, "mutually agreed terms" may not

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necessarily be mutually beneficial in reality. Corporations also often negotiate with little accountability. Even the National Cancer Institute of the U.S. (NCI), which between 1986-1991 collected some 10 000 samples representing more than 2500 species from just six Third World countries alone, has had its standard collectors' contract severely criticised. The New Scientist of 3 July 1993 reported that

"the NCI has a standard agreement which it offers countries in which its collectors hunt plants. The agreement is meant to encourage such cooperation. Australia, however, refused to sign the standard agreement when asked by the NCI in 1990. "It is a legally vacuous document", claimed the Western Australian official who is negotiating the agreement. "It would not guarantee the outcomes we require, and unless it guarantees them, why should we sign the document?"

The Australians, he says, will not agree to any deal that does not build in protection for the plant in the wild, include Australian scientists in the research and development, and guarantee a "fair and equitable share of any commercial benefits from development of the plant."

The NCI collects in 25 nations, but only 4 countries "have forced the NCI into formal agreement". (New Scientist, 10 January 1993). (13)

b) A Proposed Collector's Act

What is then suggested is a system of licensing collectors of biological diversity as a means of regulating them. The applicant will be vetted to ensure his ability to fulfill the obligations under the Act. The licence is then given for a prescribed period and subject to conditions. Any contravention of the obligations will expose the offender to penal sanctions and, as well, a withdrawal of the licence. Directors and employees of companies may be liable to imprisonment for any contravention of the Act. Licensed collectors will also be required to sign an agreement with the State (or any one it may designate or authorise on its behalf) which imposes duties on the collector before during and after the collection.

Its provisions include the collector furnishing the State with plans for prospecting, the types of material to be collected in terms of species and quantities, the evaluation, storage and use of the collected material, including the uses to which it would be put, and, the benefit the host country or community may devise from the collection of the germplasm. This is a concretisation of "the prior informed consent" of the State to which access is subjected by Article 15.5 of the Convention. By this provision consent must be given with full knowledge of its implications for the resource as well as for the sovereign rights of the State granting it.

During the collection the collector is limited to the quantum of

the resource collected, he has to keep the local community and farmers informed of his mission and supply them with duplicate samples if required. Upon collection, he has to record the most complete data: as to the plant population, its diversity, habitat and ecology sufficient to provide curators and users of germplasm an understanding of its original context; as well as document methods and technologies of using and preparing the collected material.

After collection, a series of obligations requires processing the plant samples and pathogens for conservation, depositing all collections, associated materials and records of information with the Government, transferring the samples timeously to conditions which optimise their viability, and informing the authorities of any impending threat to plant populations or evidence of accelerated genetic erosion together with recommendations for remedial action. Significantly all prospecting studies and experimentation have to be done with a collaborator (individual or institution) from the source country, such person/institution to be approved by the State.

A sum representing not less than a fixed percentage of any income arising from the supply of germplasm extracts to commercial organisations is payable by the collector. An amount is similarly payable for royalties obtained as a result of the creation or invention of a marketable product. Significantly, the collector must obtain his country's endorsement agreeing to indemnify the source country for any losses it sustains by the collector's breach of the agreement, and to deliver up the results of any report made of studies or experimentation made on the collected specimen. To prevent the usurpation of innovations of communities or indigenous people, a comprehensive obligation is imposed on the collector. It reads: "No patent application shall be filed within or outside the country in respect of the collected specimens or any part thereof, its properties or activity or any derivatives which utilise the knowledge of indigenous groups or communities in the commercialisation of any product as well as to a more sophisticated process for extracting, isolating or synthesising the active chemical in the plant extracts or compositions used by indigenous peoples or if the same represents the intellectual right of the indigenous communities" (This aspect is elaborated later in this paper.)

The agreement covers situations where although the organism is freely available from different countries, the phenotype providing an active agent from a plant is found only in the country from which it is collected.

Obligatory contracts of this kind, do not preclude parties from negotiating other terms (not in conflict with these terms) and tailoring them to their specific needs. The advantage of obliging parties to sign contracts with the Government instead of enacting subsidiary legislation to implement the Act, is that contracts are usually more easily enforceable outside the source countries. Many countries customarily have reciprocal enforcement arrangements with other countries. By this a civil judgement

obtained in the source country is enforceable in the reciprocating country upon fulfillment of certain formalities. Legislation of a country, on the other hand, has no extra-territorial effect.

c) Ex Situ Collections

The Convention excludes from its scope and ambit genetic resources obtained from source countries before the Convention came into force. This has major implications for biodiversity, especially for food and agriculture. Worldwide holdings of crop germplasm in ex situ collections (including wild relatives) amount to about 4.2 million accessions, including over two million accessions of cereals and about half a million of food legumes. The number of unique accessions is thought to be about 50% of the total number. (14)

In fact, for certain major crops they may represent for practical purposes nearly all of the world's remaining diversity. Furthermore, the actual and potential value of these collections is generally considered to be superior to most of the diversity not yet collected for the crops concerned. In addition the North effectively controls 85% of all fetal populations of domesticated livestock and 86% of global microbial culture collections - the bulk of which originates from the South.

The crop germplasm collections have been established in about 130 countries. Over half (53%) of the accessions are located in developed countries, one-third (36%) in developing countries and about 12% in international centers. However it is estimated that about 35% of the unique samples are held in the International Centers of the Consultative Group of International Agricultural Research (CGIAR). These probably comprise the most significant collection.

Who Owns these Ex Situ Genetic Materials?

FAO's Legal Office opinion given in 1987 was that regardless of where the material may have been collected from, ownership of genetic material held in government genebanks or held in public institution was, in most cases, for practical purposes considered to be vested in the State in which these genebanks are located. For material held in the International Agricultural Research Centers (IARCs) the legal position was unclear. Since 1989 the IARCs have jointly stated that they do not regard themselves as owners of the germplasm but consider that they hold them in trust for the benefit of the international community, in particular the developing countries.

The Commission on Plant Genetic Resources finding this position unsatisfactory, has called for the setting up of an International Network of base collections in genebanks under the auspices or jurisdiction of the FAO, thereby implementing FAO's International Undertaking [Article 7.1(a)]. Countries and institutions which voluntarily decide to place collections in their genebanks within this Network agree to ensure that the genetic material is safely

conserved and will be made available for plant breeding and research purposes, while respecting the rights of the providers of the germplasm. 32 countries and the IARCs, collectively holding 46% of the world's germplasm, have indicated their willingness to make their genebanks part of this International Network. IPGRI has also signed agreements with those national and international institutions registered with it to conserve specified germplasm and make it available to the international community. IPGRI has agreed to merge its register with the International Network. The combined Network will cover about 70% of global accessions.

It is crucial to understand that the granting of sovereign rights to States in their biological resources by the Convention could be effectively undermined if they are not accorded the same rights to the crop genetic resources collected from their territory and now located in these genebanks.

Ex situ collections ought to be brought within the Convention and countries originally providing the germplasm accorded sovereign rights which should entitle them to regulate access on the same basis as for in situ collections.

d) Community/Indigenous Peoples' Intellectual Rights

The State has sovereign rights over its biological resource insofar as regulating access to it. But what of the knowledge appertaining to its properties and the development of that knowledge informally, accretionally and over time, often by a community.

Existing Intellectual Property Rights (IPRs) regimes give the holder of the right an exclusive monopoly right to restrict the use (by copying, adapting, distributing) of the information embodied within the subject matter. The right to use this information can then be sold outright or its particular uses, licensed. IPRs, thus protect intangible information. The key economic advantage that accrues to intellectual property is this ability to licence for "royalties" multiple and continued use of the same piece of information.

TRIPS in GATT/WTO as discussed earlier obliges Members to provide for the protection of plant varieties by a patent system or an effective sui generis (defined as "of its own kind") system or a combination of both. The term "effective" is open to interpretation. It could well be assigned the meaning ascribed it by U.S. and corporate interests which allows patenting of all life. The term appears in the U.S. Section 301 of the Trade and Competitiveness Act 1988 and a failure to conform to U.S. IPR laws has been interpreted to mean ineffective protection. On the other hand, "effective" may also mean being coherent and consistent with the spirit and terms of the Biological Diversity Convention. Indeed the Convention exhorts Parties "to ensure that such rights (IPRs) are supportive of and do not run counter to its objectives." (Article 16.5) And its prime objectives include

the conservation of biological diversity and the fair sharing of the benefits of utilisation of genetic resources. Article 8(j) speaks of indigenous and local communities being the "holders" of knowledge, innovations and practices relating to conservation and sustainable use of biological diversity; of sharing equitably the benefits from the utilisation of such knowledge, innovations and practices. These knowledge and practices are said to be embodied in their "traditional lifestyles". Article 18.4 also urges contracting parties to advance the development and use of indigenous and traditional technologies in pursuance of its objectives. The Convention, in its Article 11, enjoins Parties to adopt economically and socially sound measures that act as incentives for the conservation and sustainable use of components of biological diversity.

Working within the parameters of the TRIPs provisions and the Convention on Biological Diversity, a sui generis legal regime for the protection of community intellectual rights could be suggested which:

- * acknowledges an alternative definition of knowledge systems which recognises the informal, collective and cumulative system of innovation of indigenous peoples and local communities.

the key

- * consonant with this, defines innovation broadly to include not just the technologically improved end-product, but as well, knowledge relating to the use (or enhanced use), of properties, values and processes of any biological resource such as any plant variety and any plant (or part of it). The definition should also be wide enough to include any alteration, modification, improvement and obtaining derivatives which utilise the knowledge of indigenous groups or communities in the commercialisation of any product as well as to a more sophisticated process for extracting, isolating or synthesising the active chemical in the biological extracts or compositions used by the indigenous peoples.

- * makes local communities/indigenous peoples custodians or stewards of such innovations, defines such rights as "non-exclusive" and "non-monopolistic" and encourages its non-commercial and free use and exchange.

- * permits such rights to be held in common with other communities/indigenous peoples.

A Model Draft Community Intellectual Rights Act, a basis for discussion, is attached as Appendix 4.

It is to be noted that these proposed community intellectual rights are not designed to meet the criteria for claiming patent rights under existing patent regimes. The proposed Model Act assumes nothing less than the evolution of new criteria compatible with the cultural values and practices of its indigenous peoples. A system to reassert these values has been

made necessary by the demands of WTO/GATT to provide for the "protection" of biological resources, plant varieties in particular.

This evolutionary process was in fact used in the service of industrial capitalism. The intellectual property system of the 19th century was a product of the industrial revolution and the inability of normal property law to protect the ideas of mechanical inventors. Plant breeders rights is a product of the 20th century development of Mendelian genetics and the inability of intellectual property systems to protect the idea of breeders. So, too, community rights (farmers' rights, more particularly, in this context of plant varieties) is a product of the era of biotechnology and the inability of other systems, in the context of new biotechnologies to protect the ideas of informal innovators. (15)

- The whole object of this Model Act is to prevent the privatisation and usurpation of community rights and knowledge through existing definitions of innovation. This is antithetical to the ethical and social values and needs of many Third World countries. It is also critical to the preservation of cultural and social life of traditional societies which embody knowledge and practices supportive of biodiversity which in turn supports livelihoods and, ultimately, life itself. It is also in accord with social justice as it recognises the true creator and respects diverse cultures and different traditions of knowledge and innovation.

The word "property" has been designedly excluded in this Model Act in describing knowledge systems of communities. Property rights in the term "intellectual property rights" as presently understood, connotes commoditisation and ownership in private hands primarily for commercial exchange. The integral elements of the relationship of the community to its knowledge is that it is uncommoditised and communally "owned" and shared. The sum total of knowledge which is of value (and not privatised) and cumulative is more aptly described by the term "community intellectual rights".

The term "innovation" is defined comprehensively and recognises the collective right in traditional knowledge of indigenous peoples. To the outside world this knowledge is indeed novel and the indigenous peoples are considered as having innovated collectively. Although the original individuals who discovered and used the knowledge lived long ago, the indigenous group which has maintained the knowledge discovered in its midst are deemed innovators. This could even satisfy the novelty requirement of the U.S. patent law: (CRS Report for Congress; Biotechnology; Indigenous Peoples, and Intellectual Property Rights, April 16, 1993, p.58). At any rate the knowledge is continuous as it modifies, adapts and builds upon the existing knowledge.

The term is also defined such as to prevent arguments based on the present U.S. patent jurisprudence which allows for the patenting of "non-obvious derivatives" or "more sophisticated

process" for extracting, isolating or synthesising the active chemical in the plant or animal extracts or compositions used by the indigenous peoples. The neem is a classic example. The neem seeds have been used as a pesticide in India for hundreds of years. Its most significant active component is azadirachtin. Patents, however, have been given to laboratory processed forms (derivates) of this naturally occurring compound as well as the process by which it is thus synthesized.

As noted earlier, prior to the emergence of property rights in plant varieties for commercial exploitation, biodiversity was in the commons of whole communities. Resources and knowledge in relation to it was freely exchanged amongst reciprocating communities who wished to use them.

The concept of an innovator monopolising the use of his innovation by excluding from or by charging for, the use of the innovation, simply did not exist. For this reason, no systematic record, oral or written was kept of who innovated, and who else used the innovation. The Model Act recognises knowledge in such form - "whether documented, recorded, oral, written or in any other such medium". In using the innovation, other innovators improve on it (Tewolde Eghziaber, 1994). This critical value is asserted by declaring communities as custodians and stewards of their, and their predecessors', collective achievements and for all time. This ensures that such knowledge always remains in the public domain and cannot therefore be usurped exclusively by commercial interests. It cannot be over-emphasised that the thrust of this Model Act is to leave intact the present non-monopolistic, non-exclusive cultural practices of indigenous peoples vis-a-vis biological resources, and not to claim monopolistic rights over them. These rights should remain in the public domain, freely accessible save where they are for commercial use. Even under the existing patent regime in the U.S., a claim for a usurpation of the right through patents is barred if the knowledge is in the public domain and therefore not novel. In Dennis v. Pitner [10b F.2d 142 (7th Cir.1939)] for example, the use of a powdered root as an insecticide and for poisoning fish was held not to be novel because, aside from scientists, Chinese gardeners and inhabitants from Peru had long used this root for the same purpose.

Two legal bases may be suggested for vesting in local communities custodianship rights of an innovation.

i) Constructive Trustee

The Biodiversity Convention acknowledges amongst other things, that indigenous and local communities are the holders of knowledge; innovations and practices in respect of the conservation and sustainable use of biological diversity [Article 8(j)].

In what capacity do they hold these rights? It is implicit that the entire community owns these rights in common. It follows then that they cannot deal with these rights without the consent of

the community. Whoever is nominated and or appointed (eg. local community leaders) to deal with these rights must necessarily hold or deal with them as trustees for the beneficiaries (the community as a whole).

This kind of trust is known in law as a constructive trust. It is a formula through which the conscience of equity finds expression to satisfy the demands of justice. When property has been acquired in such circumstances then the holder of the title (to these rights) may not in good conscience retain the beneficial interest; equity converts him into a trustee. This is accepted and trite in the jurisprudence of most civilised countries. This trust is justiciable and enforceable in Courts.

[See Snell's principles of Equity, 28th edition (1982) p. 192; *Beatty v Guggenheim Exploration Co*; (1919) 225 N.Y. 380 at 386 (Cardozo J.)]

ii) Higher Trust

It is also possible to suggest, as an alternative, that insofar as the Biodiversity Convention recognises governments as possessing sovereign rights vis-a-vis their resources, in any event, there is created a higher trust which imposes on the government an obligation to honour it in relation to those it holds the rights in trust for (that is, the community). It is settled law that although this higher trust is not enforceable in the courts, many other means are available of persuading the government to honour its governmental obligations, should it fail to do so of its own free will. It is no mere moral obligation. [Megarry V. C., in *Tito v Waddell* (No.2) (1977) 3 all E.R. 129 at 222 - a decision of the English Chancery Division Court].

Further, the right to use without acquiring ownership rights is common to many indigenous systems. For example in the Malay States of the Federation of Malaysia, early customary dealings showed that land was for use to live on and produce crops. If it was abandoned any other person could continue to use it. Land was involved as a medium rather than as an object. Popular western interpretation understood traditional land relationships on the basis of total and absolute ownership of land qualified by usufructuary proprietary rights. They conceived it according to English legal concepts to be a kind of lesser interest carved out of the total ownership when clearly the concept of total ownership was wholly alien to the Malay cultivators themselves. (16) The concept of trusteeship has also been adopted by the FAO in its resolution 4/89, which declared Farmers' Rights to be vested in the International Community "as trustees for present and future generations of farmers.."

The right is held to be in perpetuity, for, even as a community evolves, its knowledge and innovations continue their process of evolution. If indeed a duration for the protection of the right ought to be prescribed, it should commence at the start of its commercial utilisation.

Other provisions of the draft Model Act continue with the theme of keeping biodiversity within the commons of the local communities with both resources and knowledge being freely exchanged. The rationale for their inclusion are as follows:

Section 1.2 - No selling, assigning, transferring of innovation to impair status of local community as custodian of innovation.

This clause is necessary to ensure that the right inures in perpetuity and cannot be extinguished. Such a prohibition to advance public policy is common in domestic legislation. For example, legislation in Malaysia prohibits the alienation and any private dealings with land declared as Malay Reservation Land. This is to further a policy to preserve land within the perpetual possession of a designated community. Any dealing (including any contract made in relation to it) detracting from the right as custodian will then be declared illegal and of no effect.

Section 2 - Free Exchange.

This is to allow for the continuation of the customary practice of allowing for free access and exchange of innovations emanating from whole communities to other reciprocating communities. It is predicated upon the non-exclusive holding in common of knowledge innovations and practices of indigenous and local communities in respect of genetic resources and biological diversity. The free sharing does not apply if there is commercial utilisation of the innovation.

Section 3.1 - Use for Commercial Purposes.

This sub-section provides for a system of automatic entitlement of a stipulated sum to the local community which is the holder of the knowledge, innovation or practice in genetic resources in respect of any commercial utilisation of any product or process incorporating the said innovation.

It adopts a simple mode of ascertaining the payment to the community for commercial utilisation of its innovation. Such a mode of pre-fixing the mode of payment appears in the patent legislation of India in respect of payment where an innovation is compulsorily licensed for failure to use it.

Section 3.2

This sub-section recognises that the custom of some communities may eschew monetised dealings. In such an event payment shall be in a non-monetary medium. The exact mode of payment shall be decided by the community.

Section 3.3

The innovation may be used commercially by more than one person, body or corporation. This is to emphasise the non-monopolistic facet of the community innovation. This should have a beneficial effect on its wider usage and its competitive pricing. It accords

with the provision in the Biodiversity Convention to "encourage the equitable sharing of the benefits" arising from the utilisation of such knowledge, innovations and practices of indigenous and local communities [Article 8(j)].

Section 3.4

This sub-section allows for the payment to be made:

(i) where there is an organisation duly registered under the Act, to the organisation.

(ii) where there is none, to the State who holds it in trust pending the registration of an organisation.

(iii) in respect of an innovation by an indigenous or tribal community already existing in a coherent definable form as at the date of the coming into force of this Act, to the State.

This sub-section emphasises that payment shall be made in respect of all innovations past, present or future and provide for the bodies to receive payment where no formal organisation exists.

Section 3.5

This sub-section gives the local community the complete discretion to determine the disbursement of moneys (or equivalent) received in payment for their innovation.

Section 4 - Registration of Local Community.

To overcome the difficulty of defining communities (some are monolithic while others reticulated), communities can register as an organisation which will then have a legal personality with rights like any other legal person. But it is emphasised that failure to register does not alter the fact that the community concerned is and will remain the custodian of the innovation.

Section 4.2 and 4.3

These sub-sections refer to the mechanics of registration, providing particulars and changing particulars if necessary. The process is kept as expedient and simple as possible. Only a single, simple form needs to be filled upon attendance at the Registry. Attendance is thought to be important as a simple check can be undertaken to ensure that the people seeking registration are from, and represent, the community concerned.

Section 5 - Registry of Invention (ROI)

The community may register its innovation at the Registry. This will provide a simple method of giving notice to the world of the existence of the innovation. Again a saving proviso states that failure to register does not render defeasible, rights to the custodianship of the innovation. This is akin to copyright law whereby protection generally arises with no need for formal

acceptance by a registering authority. This is more flexible than patent where the written statement in the application is the primary basis upon which rights are asserted.

6. Proof of Invention.
Sections 6.1 & 6.2

To prevent prolonged dispute as to whether the knowledge, practice or technology relating to the innovation is in the custodianship of a community, a declaration by the duly constituted representatives of the community that they have been using the innovation or are the custodians of the innovation will suffice to vest the innovation in the community. The declaration will be in a manner which accords with their custom or practices.

Anyone challenging this declaration will bear the legal and evidentiary burden of so proving. (Legal burden is defined as the ultimate and main duty of proving the issue when all is said and done, failing which the case is lost. Evidentiary burden is the duty of producing sufficient evidence to raise a particular issue).

Section 7 - Technical Institution.

Identification of the innovation and their characterisation in terms intelligible to the international community requires technical capability. Some indigenous communities may not possess any. The State shall in such a situation, nominate institutions to assist the community in this respect but only in consultation with the community concerned.

Section 8 - Co-ownership

This section acknowledges that more than one community may have contemporaneously created the germplasm and the technologies or accumulated the knowledge. The innovation will in such circumstances vest jointly in all these communities and each will have complete rights and duties in relation to it save that any payments will be apportioned accordingly.

If a community collects any remuneration in respect of an innovation which is co-owned, it holds the share representing the other community's entitlement on its behalf and in trust for it.

Section 9 - Right to Bring Action

The right to pursue, present and develop the innovation and enforce rights in relation to it are vested not only in the community but also in any body, governmental or otherwise; this recognises the lack of capacity in some communities to mount any kind of action to pursue defend and enforce their intellectual rights. However, the communities' right to do so always takes precedence.

IV. Patenting Life Forms

Patenting genetic material will eventually turn all life into patentable commodities, with long term environmental, economic and ethical impacts. The battle over the past decade in the U.S and Europe has been the extent to which private enterprise can own genetic material. National patent legislation, where they exist, have consistently rejected the patenting of plants and animals, let alone human genes. The Indian Patents' Act is a good model for the balancing of the private interest of corporations and the public good. Exclusions of patents are clearly laid out, reflecting the social, cultural and ethical values of the society, its economic priorities and sovereignty.

Article 27(3)(b) of the TRIPs provision in the GATT Final Act (17) appears to exclude plants and animals from being patented. However, the same phrase in the U.S. patent legislation ("plants and animals other than microorganisms") has not prevented the U.S. Patent and Trademark Office and courts of law from allowing patenting of more and more life forms. The first patent on life was recognised by the U.S. Supreme Court in the Chakrabarty case in 1980 when genetically engineered *Pseudomonas* bacteria was accepted by the court as an invention of the scientist and therefore was patentable. The genetically modified microorganism was not considered a product of nature. Yet Chakrabarty himself had stated that he "simply shuffled genes" and was not creating life, ("It's like teaching your pet cat a few new tricks."), when the Patent Office rejected the initial application on the grounds that animate life forms were not patentable. The significant outcomes of this judicial decision are:

- (a) microorganisms thus modified are not regarded as "naturally occurring", and can therefore be patented; and
- (b) modification of genetic materials is treated as "creation", thereby allowing ownership of any altered biological material.

The slippery slope towards ownership of all life was thus created by this Supreme Court decision. (18) In 1988 the first patent on a living animal (a genetically engineered mouse for cancer research) was approved for Dupont. The company now has patent ownership over any animal species whose genelines are engineered to contain a variety of cancer-causing genes. There are over 190 genetically animals, including cows, pigs, mice and fish awaiting patenting in the U.S. The escalating use of biotechnology has gone beyond traditional breeding of plants and animals to cross-species genetic transfers involving human genes too. For the first time a patent has been applied for a technique for human "germ-line therapy" - treatment to change genetic traits that would be passed on down the generations. The idea of altering genes in the reproductive cells was deemed "unthinkable" as it raises the ugly spectre of eugenics: The Director of the European Patent Office, which is processing this application says a decision will have to be made "if it's ethical or not to grant

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this patent".

The phrase "plants and animals other than microorganisms" also does not cover parts or clones of these biological materials, again allowing for compulsory patenting and rendering the exclusion clause of TRIPs meaningless. This loophole has been successfully exploited by industry in the U.S.

Article 27 as it stands is unacceptable, and Southern governments should have this reviewed and rejected in the GATT/WTO. The Parties to the Biodiversity Convention should accordingly reject a similar regime and spell out clearly a genuine exclusion of patenting, under existing conditions, of the following: "biological organisms and their parts and processes and any products therefrom, including but not limited to any such organisms, parts, products, information or processes derived from genetic engineering or similar techniques."

V. Biosafety

The biotechnology industry plans to release a wide range of genetically modified organisms (GMOs) into the environment, creating unknown health and environmental hazards that cannot be recalled. The very biological resources which the Convention aims to protect could be threatened by such releases.

Public accountability by researchers and industry for the hazards of biotechnology which is protected by IPRs, will accordingly be eroded because IPRs as they are globally promoted are primarily designed for the interest of private industry, and hides the ignorance about the ecological and health impacts of new technologies. Ignorance about the ecological and health impacts of new technologies has far outweighed the knowledge needed for their production. Indeed ignorance rather than knowledge characterises our times, and maintaining an ignorance about our ignorance is a central taboo of the technocratic culture. It took two hundred years of production based on fossil fuel before scientists realised that its burning has unanticipated side effects - climate destabilisation, atmospheric pollution and the greenhouse effect. DDT was celebrated as an ultimate tool for ensuring public health. A Nobel Prize was awarded for its discovery. Today DDT and other toxic pesticides are known to carry very high ecological and health costs, and many have been banned in the industrialised countries.

Because they are alive, genetically engineered products are inherently more unpredictable than chemical products. They can reproduce, mutate and migrate. They cannot be recalled. Wheale and McNally report that recent research has shown that genetic manipulation of harmless viruses can turn them virulent. There are no "safe" bioengineered viruses. There is no real predictive ecology because the way in which genetically modified life forms interact with other organisms, and in different environments, is uncharted territory. (19)

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The claim to patent germ-line gene therapy, whereby spermatogonia - the primitive reproductive cells that ultimately develop into sperm, genetically modifying them, and repopulating the testes with the "corrected spermatogonia", has been described as "far too risky a technology" by the Director of the Office of Recombinant DNA Activities at the U.S. National Institute of Health.

As bans and regulations delay tests and marketing in the North, biotechnology products will increasingly be tested in the South to bypass regulation and public control. Dr Alan Goldhammer of the Industrial Biotechnology Association of the U.S. states that "the pathway maybe clearer in foreign nations to getting approval". There is an urgent need for stronger systems of laws and controls to assess and screen the development of biotechnology in the home country, which should be simultaneously accompanied by similar assessment and screening of transfers to the South. IPRs can be a fundamental obstacle because they protect industry's interest and often cover up the ignorance of the impacts of biotechnology processes and its products. It is thus critical that a Biosafety Protocol be negotiated in accordance with Article 19(3) of the Biodiversity Convention.

VI. PROPOSALS

The following proposals are therefore suggested.

1. There should be no patenting of any life forms including microorganisms and genetic materials, or any part thereof, or any altered form thereof, or any processes including genetic engineering and similar techniques. The provisions in the GATT/WTO should be clarified/altered accordingly.

2. Third World countries should consider enacting national legislation along the Model Acts as proposed:

- a) licencing collectors and regulating access to biological resources, and
- b) recognising the intellectual rights of indigenous and local communities.

3. Ex situ collections should be brought within the Convention and countries from whence the original germplasm was collected be accorded sovereign rights which entitles them to regulate access in the same way as for in-situ collections.

4. Genetically modified organisms are living organisms which can be subject to "genetic shuffling". They should therefore not be patentable. The term "naturally occurring biological material" should be defined to include altered biological material.

5. Technologies, especially biotechnologies, should be assessed and screened for their hazards to biodiversity, the environment, human health and their adverse impact on economies and peoples' livelihoods especially in the Third World; there should be an urgent formulation of a biosafety protocol.

FOOTNOTES

- (1) For general information on this, see Vandana Shiva, "Monocultures of the Mind", Third World Network, 1993
- (2) Vandana Shiva, *ibid.*
- (3) Rights of indigenous and local communities embodying traditional lifestyles: Note by ICCBD Interim Secretariat, 1994, (hereafter "Note"), citing Kloppenburg, J. Jr., "No Hunting! Biodiversity, Indigenous Rights, and Scientific Poaching." Cultural Survival Quarterly, Summer 1991, page 15.
- (4) Note, citing, Elisabetsky, E. "Folklore, Tradition or Know-How? The ethno-pharmacological approach to drug discovery depends on our ability to value non-Western knowledge of medicinal plants." Cultural Survival Quarterly Summer 1991 page 10.
- (5) Note, citing, Gray, Andrew, Between the spice of life and the melting pot: Biodiversity conservation and its impact on indigenous peoples. International Working Group for Indigenous Affairs (IWGIA), document 70, 1991.
- (6) Farnsworth, et al, (1985) "Medicinal Plants in Therapy," Bulletin of WHO 63, p.965-966.
- (7) Note, citing, Balick, *Michael. Ethnology and the identification of therapeutic agents from the rainforest. In D.J. Chadwick and J.Arsh, eds., Bioactive Compounds from Plants, 1990.
- (8) Note, citing, Gray, A. "Indigenous Peoples and the Marketing of the Rainforest.", The Ecologist, Vol. 20, No. 6, 1991; and Posey, D. "Intellectual Property Rights and Just Compensation for Indigenous Knowledge." Anthropology Today, vol. 6 No. 4 August 1990
- (9) Id. Posey at 15
- (10) Note, citing, Stephen Brush, "Indigenous Knowledge of Biological Resources and Intellectual Property Rights: The Role of Anthropology", American Anthropologist, 95 (3): 653-686 (1993). Brush notes that crop germplasm is stored in quantity in industrialised countries and in international agricultural research institutions and may be both more valuable and accessible than uncollected germplasm. He states that currently the supply of collected crop germplasm exceeds demand.
- (12) The UN Conference on Environment and Development (UNCED) held in Rio de Janeiro, Brazil in June 1992 was the largest ever gathering to focus on environmental issues. UNCED was a process not a single event. Seventy percent of the negotiations were completed in the Preparatory Committee Meetings, conducted prior to the Rio Summit. The Biodiversity Convention was thus negotiated in a separate but parallel process to that of UNCED, and opened for signing in Rio.

(11) Progress report on Resolution 3 of the Nairobi Final Act, FAO, supra, p.5.

(13) R. Kiew and Nordin Hj. Lajis, "The commercial exploitation of biodiversity with special reference to Malaysia", 1994.

(14) Farmers' Rights, RAFI Communique. May/June 1989.

(15)

(16) See David Wong, Tenure and Land Dealings in the Malay States, Singapore University Press, 1975 p. 8-13. Baden-Powell critical of any attempt to define cultivator's relationship with land under native customs in terms of western concepts said, after giving a descriptive account of the customs of the native cultivators in India: "These are the facts of the tenure; you may theorise on them as you please; you may say this amounts to proprietorships, or this is a dominium minus plenum, or anything else." (Baden-Powell, Land Revenue and Land Tenure in India, Oxford 1894, p.138)

(17) Article 27(3)(b) of the TRIPs provision of the GATT Final Act reads as

"Members may also exclude from patentability, plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective *sui generis* system or a combination thereof. The provisions of this subparagraph shall be reviewed four years after the date of entry into force of the WTO Agreement."

(18) Andrew Kimbrell, "The Human Body Shop" (1993)

(19) "Genetic Engineering: Catastrophe or Utopia" (Harvester, 1988)

APPENDIX 1

EXPLANATORY NOTE ON FAO GLOBAL SYSTEM

In 1983 the member countries of FAO established (a) a permanent intergovernmental forum on plant genetic resources: the Commission on Plant Genetic Resources (CPGR), and, (b) a legal framework: the International Undertaking on Plant Genetic Resources.

This constitutes the FAO Global System for the Conservation and Utilization of Plant Genetic Resources. It initially covered food and agriculture and later extended to animal and fish biodiversity.

This system is co-ordinated, overseen and monitored by the CPGR.

The objectives of this Global System are to ensure the safe conservation and to promote the availability and sustainable utilisation of plant genetic resources for present and future generations by providing a flexible framework for sharing the benefits and burdens. The system covers both ex situ and in situ conservation, and plant genetic resources covers genes, genotypes and gene pools.

140 countries are formally part of the System, 123 are members of the Commission and 110 have adhered to the International Undertaking (IU). This IU was adopted by the FAO Conference Resolution 8/83, with 8 reservations - USA, United Kingdom, France, Germany, Switzerland, Canada, New Zealand and Japan. It was the first comprehensive international agreement concerning plant genetic resources.

The Undertaking is not legally binding. Its object is 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".

In order to overcome the reservation to the IU, it has been further qualified and interpreted by a number of complementary resolutions which were negotiated by countries through the CPGR and adopted unanimously by the FAO Conference. These resolutions are:

- 4/89: provided an agreed interpretation of the IU affirming that PBRs as provided by UPOV Convention of 1978 were not inconsistent with the IU. It simultaneously recognised "Farmers' Rights"
- 5/89: defined Farmers' Rights.
- 3/91: reaffirmed "common heritage of mankind" concept subject to the sovereign rights of nations over their genetic resources agreed that Farmers' Rights will be implemented through an international fund on CPGR.

7/93: Countries agreed that the IU would be revised.



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EXPLANATORY NOTES TO CIRA

INTRODUCTION

The object of the Act is to provide for a system which:

- a) acknowledges the innovative contribution of local communities in respect of genetic resources and the conservation of biological diversity.
- b) acknowledges that biodiversity has been and should remain, the commons of local communities with both resources and knowledge being freely exchanged.
- c) establish that anyone accessing these resources and knowledge for commercial advantage must pay the community for such access.
- d) that such access shall be non-exclusive.

1. Definitions

"Innovation" - Section 1 (c)

The existing legal framework for intellectual property rights recognises only the Northern industrial model of innovation. It has failed to recognise the more informal, communal system of innovation through which Southern farmers and indigenous communities produce, select, improve and breed a diversity of crop and livestock varieties and, often, over a long period of time. It also fails to take into account the traditional knowledge of indigenous communities.* Essentially this is a clash of the definition of knowledge systems.

It is therefore proposed to define "innovation" which recognises the collective and cumulative intellectual right of such communities as a corollary to protecting it. Additionally, the definition recognises such knowledge howsoever recorded, whether formally or informally (orally, anecdotal, etc.,). This is to take account of communities in the Third World which may not have a written tradition or culture.

[* Although it is widely acknowledged that without the input of indigenous knowledge, many valuable medicinal products used extensively throughout the modern world would not exist. For example, of the 120 active compounds currently isolated from the higher plants and widely used in medicine today, 74 percent show a positive correlation between their modern therapeutic use and the traditional use if the plant from which they were derived. Farnsworth, et al, (1985) "Medicinal Plants in Therapy," Bulletin of WHO 63, 965-6.]

The term is comprehensively defined to prevent arguments based on the present U.S. patent jurisprudence which allows for the patenting of "non-obvious derivatives" or "more sophisticated process for extracting, isolating or synthesizing the active chemical in the plant or animal extracts or compositions used by the indigenous people. The neem is a classic example. The neem seeds have been used as a pesticide in India for hundreds of years. Its most significant active component is azadirachtin. Patents, however, have been given to laboratory processed forms (derivates) of this naturally occurring compound as well as the process by which it is thus synthesized.

The word "property" has been designedly excluded in describing knowledge systems of communities. Property rights in the term "intellectual property rights" as presently understood, connotes commoditisation and ownership in private hands primarily for commercial exchange. The integral elements of the relationship of the community to its knowledge is that it is uncommoditised and communally "owned" and shared. The sum total of knowledge which is of value (though not necessarily priced) in communal control (and not privatised) and cumulative is more aptly described by the term "community intellectual rights".

2. Concept of Custodianship and Stewardship: Section 1

The emergence of property rights in plant varieties for commercial exploitation came about with the enactment of an International Convention - the Union for the Protection of New Varieties of Plants (UPOV), first negotiated in the early 1960's. It gave property rights to plant breeders for improved varieties on a basis similar to that required to obtain a patent of an industrial product, namely, novelty, industrial application and originality. Prior to this biodiversity was in the commons of whole communities. Resources and knowledge in relation to it was freely exchanged amongst reciprocating communities who wished to use them.

The concept of an innovator monopolising the use of his innovation by excluding from, or by charging for, the use of the innovation, simply did not exist. For this reason, no systematic record, oral or written was kept of who innovated, and who else used the innovation. In using the innovation, other innovators improve on it (Tewolde, 1994). This clause then restates this critical value by declaring communities as custodians and stewards of their, and their predecessors, collective achievements.

Section 1.1

This section vests in the local community the right of custodianship or stewardship of an innovation. On what basis can this right be founded? Two bases can be suggested.

a) Constructive Trustee.

The Biodiversity Convention acknowledges amongst other things, that indigenous and local communities are the holders of knowledge innovations and practices in respect of the conservation and sustainable use of biological diversity (Article 8 (j)).

In what capacity do they hold these rights? It is implicit that the entire community owns these rights in common. It follows then that they cannot deal with these rights without the consent of the community. Whoever is nominated and or appointed (eg. local community leaders) to deal with these rights must necessarily hold or deal with them as trustees for the beneficiaries (the community as a whole).

This kind of trust is known in law as a constructive trust. It is a formula through which the conscience of equity finds expression to satisfy the demands of justice. When property has been acquired in such circumstances then the holder of the title (to these rights) may not in good conscience retain the beneficial interest; equity converts him into a trustee. This is accepted and trite in the jurisprudence of most civilised countries. This trust is justiciable and enforceable in Courts.

(see Snell's principles of Equity, 28th edition (1982) p. 192; Beatty v Guggenheim Exploration Co;, (1919) 225 N.Y. 380 at 386 (Cardozo J.).

b) Higher Trust

It is also possible to suggest, as an alternative, that insofar as the Biodiversity Convention recognises Governments as possessing sovereign rights vis-a-vis their resources, in any event, there is created a higher trust which imposes on the Government an obligation to honour it in relation to those it holds the rights in trust for (that is, the community). It is settled law that although this higher trust is not enforceable in the courts, many other means are available of persuading the Government to honour its governmental obligations, should it fail to do so of its own free will. It is no mere moral obligation. (Megarry V.C., in Titō v Waddell (No. 2) (1977) 3 All E.R. 129 at 222 - a decision of the English Chancery Division Court).

Further, the right to use without acquiring ownership rights is common to many indigenous systems. For example in the Malay States of the Federation of Malaysia, early customary dealings showed that land was for use to live on and produce crops. If it was abandoned any other person could continue to use it. Land was involved as a medium rather than as an object. Popular western interpretation understood traditional land relationships on the basis of total and absolute ownership of land qualified by usufructuary proprietary rights. They conceived it according to English legal concepts to be a kind of lesser interest carved out of the total ownership when clearly the concept of total ownership was wholly alien to the Malay cultivators themselves

(see David Wong, Tenure and Land Dealings in the Malay States, Singapore University Press, 1975 pp.8-13). Baden-Powell critical of any attempt to define cultivator's relationship with land under native customs in terms of western concepts said, after giving a descriptive account of the customs of the native cultivators in India: "These are the facts of the tenure; you may theorise on them as you please; you may say this amounts to proprietorships, or this is a dominium minus plenum, or anything else." (Baden-Powell, Land Revenue and Land Tenure in India, Oxford, 1894, p.138)

Section 1.2 - No selling, assigning, transferring of innovation to impair status of local community as custodian of innovation.

This clause is necessary to ensure that the right inures in perpetuity and cannot be extinguished. Such a prohibition to advance public policy is common in domestic legislation. For example, legislation in Malaysia prohibits the alienation and any private dealings with land declared as Malay Reservation land. This is to further a policy to preserve land within the perpetual possession of a designated community. Any dealing (including any contract made in relation to it) will then be declared illegal and of no effect.

Section 2 - Free Exchange.

This is to allow for the continuation of the customary practice of allowing for free access and exchange of innovations emanating from whole communities to other reciprocating communities. It is predicated upon the non-exclusive holding in common of knowledge innovations and practices of indigenous and local communities in respect of genetic resources and biological diversity. The free sharing does not apply if there is commercial utilisation of the innovation.

Section 3.1 - Use for Commercial Purposes.

This sub-section provides for a system of automatic entitlement of a stipulated sum to the local community which is the holder of the knowledge, innovation or practice in genetic resources in respect of any commercial utilisation of any product or process incorporating the said innovation.

It adopts a simple mode of ascertaining the payment to the community for commercial utilisation of its innovation. Such a mode of pre-fixing the mode of payment appears in the patent legislation of India in respect of payment where an innovation is compulsorily licensed for failure to use it.

Section 3.2

This sub-section recognises that the custom of some communities may eschew monetised dealings. In such an event payment shall be in a non-monetary medium. The exact mode of payment shall be decided by the community.

Section 3.3

The innovation may be used commercially by more than one person, body or corporation. This is to emphasise the non-monopolistic facet of the community innovation. This should have a beneficial effect on its wider usage and its competitive pricing. It accords with the provision in the Biodiversity Convention to "encourage the equitable sharing of the benefits" arising from the utilisation of such knowledge, innovations and practices of indigenous and local communities (Article 8 (j)).

Section 3.4

This sub-section allows for the payment to be made:

- (a) where there is an organisation duly registered under the Act, to the organisation.
- (b) where there is none, to the State who holds it in trust pending the registration of an organisation.
- (c) in respect of an innovation by an indigenous or tribal community already existing in a coherent definable form as at the date of the coming into force of this Act, to the State.

This sub-section emphasises that payment shall be made in respect of all innovations past, present or future and provide for the bodies to receive payment where no formal organisation exists.

Section 3.5

This sub-section gives the local community the complete discretion to determine the disbursement of moneys (or equivalent) received in payment for their innovation.

Section 4 - Registration of Local Community.

To overcome the difficulty of defining communities (some are monolithic while others reticulated), communities can register as an organisation which will then have a legal personality with rights like any other legal person. But it is emphasised that failure to register does not alter the fact that the community concerned is and will remain the custodian of the innovation.

Section 4.2 and 4.3

These sub-sections refer to the mechanics of registration, providing particulars and changing particulars if necessary. The process is kept as expedient and simple as possible. Only a single, simple form needs to be filled upon attendance at the Registry. Attendance is thought to be important as a simple check can be undertaken to ensure that the people seeking registration are from, and represent, the community concerned.

Section 5 - Registry of Invention (ROI)

The community may register its innovation at the Registry. This will provide a simple method of giving notice to the world of the existence of the innovation. Again a saving proviso states that failure to register does not render defeasible, rights to the custodianship of the innovation.

6. Proof of Invention. Sections 6.1 & 6.2

To prevent prolonged dispute as to whether the knowledge, practice or technology relating to the innovation is in the custodianship of a community, a declaration by the duly constituted representatives of the community that they have been using the innovation or are the custodians of the innovation will suffice to vest the innovation in the community. The declaration will be in a manner which accords with their custom or practices.

Anyone challenging this declaration will bear the legal and evidentiary burden of so proving. (Legal burden is defined as the ultimate and main duty of providing the issue when all is said and done, failing which the case is lost. Evidentiary burden is the duty of producing sufficient evidence to raise a particular issue.)

Section 7 - Technical Institution.

Identification of the innovation and their characterisation in terms intelligible to the international community requires technical capability. Some indigenous communities may not possess any. The State shall in such a situation, nominate institutions to assist the community in this respect but only in consultation with the community concerned.

Section 8 - Co-ownership

This section acknowledges that more than one community may have contemporaneously created the germplasm and the technologies or accumulated the knowledge. The innovation will in such circumstances vest jointly in all these communities and each will have complete rights and duties in relation to it save that any payments will be apportioned accordingly.

If a community collects any remuneration in respect of an innovation which is co-owned, it holds the share representing the other community's entitlement on its behalf and in trust for it.

Section 9 - Right to Bring Action

The right to pursue, present and develop the innovation and enforce rights in relation to it are vested not only in the community but also in any body, governmental or otherwise; this recognises the lack of capacity in some communities to mount any kind of action to pursue defend and enforce their intellectual

rights. However, the communities's right to do so always takes precedence.



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COLLECTORS OF BIOLOGICAL AND ~~PLANT GENETIC~~ RESOURCES (CONTROL & LICENSING) ACT

An Act to provide for the control regulation and licensing of collectors of biological and ~~plant genetic~~ resources and for matters connected therewith.

1. This Act may be cited as the Collectors of Biological ~~And Plant Genetic~~ Resources (Control & Licensing) Act.

2. In this Act unless the context otherwise requires

"body of persons" means a group of persons not being an incorporated body or group;

"collector" means any individual body of persons, company or firm or institution or any one or more of them engaged or involved in the collection of biological ~~or other plant genetic~~ resources whether as a business or howsoever otherwise situated within the jurisdiction of Malaysia.

"company" means any company incorporated, formed or registered under any written law for the time being in force in Malaysia relating to companies and includes any body incorporated or established under any law in force in Malaysia.

"Controller" means the Controller of Biological & ~~Plant Genetic~~ Resources appointed under this Act.

"Convention" means the Convention on Biological Diversity.

"firm" means an unincorporated body of persons associated together for the purpose of carrying on business.

"inspector" means an inspector appointed under this Act.

"licensed collector" means any collector licensed under this Act to engage in or carry on or

undertake the collection of biological and plant genetic resources whether as a business, on a one-off occasion or howsoever otherwise.

"prescribed" means prescribed by the Minister under this Act.

3. For the purpose of this Act the Minister may appoint an officer to be styled the Controller of Biological and ~~Plant Genetic Resources~~ and such number of Inspectors of Biological and ~~Plant Genetic Resources~~ and other officers and servants as the Minister may deem fit.

4 (1) No collection of biological ~~or other plant genetic~~ resources shall be engaged in, carried on or undertaken except by a collector in possession of a licence issued under the Act.

(2) A collector who desires to engage in or carry out or undertake the collection of biological and ~~plant genetic~~ resources may apply to the Controller for a Licence and any such application shall be made in the prescribed form and in the case of any applicant listed in column (1) of the Schedule the application shall be accompanied by the document listed against him in Column (2), every such document being verified by means of a statutory declaration made by the person listed in Column (3) of the said Schedule.

(3) Upon receiving an application for a licence under this section, the Controller may grant the licence applied for or refuse to grant such a licence; and in granting such a licence the Controller may impose thereon such conditions (including the period during which the licence shall be valid) as he may deem fit and proper.

(4) Subject to Section 8, the Controller may at any time vary, cancel or alter the conditions aforesaid or impose any new or additional conditions; or, where the licence is not subject to any condition, impose thereon such conditions as the Controller may deem fit for carrying out the provisions of this Act.

Provided that no restrictions/conditions shall be imposed which run counter to the Convention.

5. (1) Subject to the exercise of power of waiver by the Minister under subsection (2), the licence applied for under Section 4 shall not be granted unless the

Controller is satisfied that :

- (a) the collector is financially sound;
- (b) the Collector is in a position to meet his obligations under this Act;
- (c) unless the applicant is not himself nor is any member or partner thereof a person convicted of an offence involving fraud or dishonesty or an undischarged bankrupt, if the application is made respectively by a person or a body of persons or a firm; and
- (d) unless no one who is convicted of an offence involving fraud or dishonesty or who is an undischarged bankrupt is holding office as director, manager or secretary or other similar office or position, if the application is made by a company, or is holding office as president, secretary or treasurer or other similar office or position, if the application is made by a society.

(2) The Minister may in his absolute discretion waive any or all of the conditions set out in subsection (1) (a), (b) or (d) or substitute any or all of the said conditions or such other conditions as he may consider fit and proper.

6. The Minister may give to a licensed controller such directions as he considers fit and proper for the purpose of ensuring compliance with this Act, and any such direction shall be made in writing and shall be binding on the licensed controller to whom the direction is made.

7. If any licensed controller -

- (a) is carrying on his undertaking, in the opinion of the controller, in a manner detrimental to the interest of the public;
- (b) has insufficient assets to cover his liabilities;
- (c) is contravening any of the provisions of this Act; or
- (d) has ceased to carry on the undertaking

the Controller may subject to the provision of section 8 relating to the giving of opportunity of being heard, revoke the licence issued to the licensed Collector or suspend for such period as the Controller may determine.

8. Before revoking or suspending a licence under Section 7 or before varying, cancelling or altering any conditions imposed on a licence or before imposing thereon any new or additional conditions under Section 4(4), the Controller shall notify the collector who is affected by the action proposed to be taken by the controller of the aforesaid proposed action and shall give the licensed collector an opportunity to submit reasons or an explanation why the aforesaid proposed action should not be carried out.

9. An applicant applying under Section 4(3) or a licensed collector, as the case may be, who is aggrieved by the action or decision of the Controller

a. in refusing to grant a licence to him under Section 4(3);

b. in varying, altering or cancelling any conditions of his licence or imposing thereon any new or additional conditions under Section 4(4);

c. in revoking or suspending his licence under Section 7;

may within fourteen days after having been notified of the action or decision of the Controller appeal against that action or decision to the Minister; and the decision of the Minister made thereon shall be final and shall not be questioned in any Court..

10. No action shall lie against the Government, the Minister, the Controller, Inspector or against any officer of the Government or any person acting under the direction of the Minister, the Controller or Inspector for damages in any civil court for anything bona fide done, ordered or omitted to be done pursuant to this Act; and all actions which may lawfully be brought in respect of anything done, ordered or omitted to be done pursuant to this Act shall be instituted within six months from the date of the act of omission complained of, and not afterwards.

11. Any collector who -

(a) in contravention of Section 4(1) engages in, carries out, or undertakes collection of biological and natural resources without having been duly licensed under that section;

(b) fails to comply with any of the conditions imposed on the licence granted under Section 4;

(c) fails to comply with any direction given by the Minister under Section 6;

(d) removes any biological material out of the country without the prior written authorisation of the appropriate authority shall be guilty of an offence and shall, on conviction, be liable to a fine not exceeding twenty thousand dollars or to imprisonment for a term not exceeding five years or to both.

12. (1) Where any offence against any provisions of this Act has been committed by a licensed collector, any person who at the time of the commission of the offence was a director, manager or secretary or holds any similar office or position or was an agent, clerk or servant of the licensed controller shall be deemed to be guilty of that offence, unless he proves that the offence was committed without his consent or connivance and that he exercised all such diligence to prevent the commission of the offence as he ought to have exercised, having regard to the nature of his functions in that capacity and to all the circumstances, and shall, on conviction, be liable to imprisonment for a term which shall not be less than twelve months but which shall not exceed three years and shall also be liable to a fine not exceeding ten thousand dollars.

(2) Any person liable under this Act to any punishment or penalty for any act or omission shall be liable to the same punishment or penalty for any such act or omission by -

- a. his partner;
- b. his agent acting on his behalf;
- c. his clerk or servant acting in the course of his employment; or
- d. the clerk or servant of his partner or

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agent acting in the course of employment in circumstances that had the act or omission been committed by the partner or agent the aforesaid person would have been liable under this subsection:

Provided that nothing herein shall relieve the partner, agent, clerk or servant or the clerk or servant of that partner or agent from liability to prosecution.

13. (1) The Minister shall prescribe the form of contract which shall be used by a licensed Collector, his agent nominee or the party/institution or body responsible for the resources both as a condition of the grant of a licence under this Act or otherwise.

(2) In the said contract the Minister shall regulate the conditions and terms of any such contract as aforesaid in sub-section(1) hereof.

(3) No amendment to any such contract shall be made except on the ground of hardship or necessity and with the prior approval in writing of the Controller.

(4) Every such contract shall be as prescribed in Schedule I.

SCHEDULE I

CONTRACT BETWEEN THE COLLECTOR AND THE
GOVERNMENT PARTIES

An Agreement made this day between
of
(hereafter referred to as "the Collector") an
of on
behalf of the Government of Malaysia (hereafter "the
Government").

RECITALS

WHEREAS The Collector is desirous of
engaging in or carrying on or undertaking the
collection of biological resources and has been duly
licensed to do so by the Government.

AND WHEREAS the Government has the
sovereign right vis-a-vis the Collector of the
biological resource to be collected and is desirous
of permitting the Collector to collect the said
resource.

AND WHEREAS all parties hereto
shall observe International Conventions (in-
cluding the Biological Diversity Convention) and
Codes (including the Code of Conduct for Plant
Germplasm Collecting and Transfer of the Commission
on Plant Genetic Resources), and,

shall have regard to the sustainable collec-
tion of specimens while conserving the biological
diversity of the country and respecting and
acknowledging the cumulative communal and
traditional knowledge, innovations and practices
relevant to the conservation of biological diversity
and the sustainable use of its components and the
close and traditional dependence of many indigenous
and local communities embodying traditional
lifestyles on biological resources.

DEFINITIONS

- a. "Active ingredient" means
- b. "Biological diversity" refers to the varieties of all life forms - plants, animals and microorganisms, the genes they contain and the ecosystems of which they form a part.
- c. "Caretakers" means local communities and/or local farmers, who maintain genetic diversity in their environments and farming systems.
- d. "Collaborator" means the national party, organisation or institution named by the Collector in collaboration with whom the Collector shall engage in the activity referred to in clause 1.
- e. "Collector" means any corporation, organisation or person licensed under the laws of this country to collect biological resources and related information.
- f. "Curator" means a person or organization, within the host country or elsewhere, that conserves and manages biological resources and related information.
- g. "Designated Appropriate Authority" means the Government of Malaysia acting through the Minister of Agriculture or such other Ministry, organisation, body or person as shall be designated by the Government;
- h. "Ex situ conservation" means the maintenance of organisms or their genetic material away from their natural habitat.
- i. "Farmers' rights" means rights arising from the past, present and future contributions of farmers in conserving, improving, and making available biological resources, particularly those in the centres of origin/diversity.
- j. "Genetic erosion" means loss of genetic diversity.
- k. "In situ conservation" means the maintenance of organisms in their natural habitat, or, in the case of domesticated organisms in the area where they have developed their distinctive properties.

l. "Natural product" means a product of a plant, animal or micro-organism and includes their parts and processes and any products however derived therefrom.

m. "Plant genetic resources" or "plant germplasm" means the reproductive or vegetative propagating material of plants.

n. "the Government" means where the context so admits, the Government of Malaysia acting through its Ministries or agents or servants;

o. "the foreign Government" means where the context so admits, the Government of the country where the Collector ordinarily resides and which endorses this contract under Clause 8(1) hereof;

NOW BY THIS DEED IT IS HEREBY AGREED AS FOLLOWS :

1. The Government hereby authorises the Collector to engage in the collection of biological resources namely, for the period beginning on _____ and ending on _____.

2. The Collector shall upon the execution of this agreement :

(1) furnish the Government with plans for the collector's activity including in particular:

- a. the types of material to be collected in terms of species and quantities;
- b. the plan for the evaluation, storage and use of the material collected;
- c. the use or uses to which the collected material will be put; and
- d. the benefit the host country/community may derive from the collection of the germplasm;
- e. financial arrangements for the collection.

(2) provide the Government with the names, addresses and particulars of their collaborators from a list drawn up and approved by the Government and which may include :

- a. national scholar(s);
- b. scientist(s);
- c. non-governmental organisation(s)
- d. Institution(s).

(3) supply details of any agreement made with the said collaborator, the names of persons who will assist in the said collection and in any event the names and complete particulars of 2 persons nominated by the collaborators to accompany the collection mission.

(4) undertake to abide by the country's natural product policy, quarantine procedures, the cultural practices, traditional values and customs of local communities and all relevant laws and regulations.

3. The Collector shall, in the period during collection:

(1) Not collect more than 100-150 grams (dry weight) of the resource for initial screening save with the permission in writing of the Government.

(2) Inform local communities concerned as to

- a. the purpose of the mission;
- b. how and where samples of the ~~col~~ collected biological resource could be ^{obtained by} the local community and
- c. their entitlement to obtain from the Collector duplicate samples.

(3) Whenever samples for bioactivity screening are collected,

- a. keep a written record which describes in detail the biological resource particularly its conservation status, locality, its diversity, habitat and ecology such as is sufficient to provide curators and users of the resource an understanding its original context.

4. The Collector shall, after collection:

- (1) process within _____ weeks

thereafter, "within the jurisdiction unless otherwise agreed to in writing, the biological samples that have been collected for conservation;

(2) prepare in writing the relevant written record;

(3) deposit duplicate sets of all collections and associated materials and records of information, including that referred to in Section 3(3) hereof, with the Government and the following additional persons/institutions, namely, _____;

(4) obtain the phytosanitary certificate(s) and other documentation necessary for transferring the material collected, where such transfer is permitted by the Government;

(5) inform the appropriate authorities about any impending threat to plant populations, or evidence of accelerated genetic erosion, and make recommendations for remedial action;

(6) supply to the Government a consolidated report on the collecting mission, including :

a. the localities visited,

b. the confirmed identification and other relevant data of the biological samples collected; ~~and~~

5. The Collector shall, in addition

(1) at all times, wherever possible, make any study and experimentation involving the specimens within the country and with full participation of the collaborator, save as otherwise agreed to in writing by the collaborator and the Government;

(2) submit to the Government any report or writing concerning studies or experimentation made on any specimen collected; and

(3) ensure that the collaborators or, in the case of NGOs or Institutions, their duly nominated persons, shall join in the work in the laboratories or trial sites where any specimen collected is the subject of any biotechnological experimentation or study. In such event the Collector shall finance the participation as aforesaid of the collaboration upon terms mutually acceptable to the Collector on the one part and the collaborator and the Government on the other part.

6. A sum representing not less than 60% of any income arising from the supply of natural product extracts to commercial organisations shall be paid

a. in the case of resources held in custody by local communities as set out under the Community Intellectual Rights Act (CIRA), to the Community or such organisations or authority designated by the said Act; and

b. in all other cases, to the Government.

PROVIDED that if a greater sum is set out under CIRA the said sum shall be substituted for the sum payable under this section; and

PROVIDED FURTHER that payment shall be made equally to instances as set out in clause 9(5) hereof.

7. A sum representing not less than 51% of any royalties obtained as a result of the creation or invention of a marketable product is payable in the same manner as clause 6(a) and (b) hereof and subject to the same proviso as set out in clause 6 hereof and provided also that payment shall be made equally to instances as set out in Clause 9(5) hereof.

8. (1) The Collector shall obtain the endorsement of this contract by the duly constituted authority of the Government of his country/sponsor organisation, signifying, inter alia,

(a) its agreement that in the event of a breach of any terms of this agreement it shall indemnify the Government of Malaysia, or the appropriate community in respect of any losses, expenses, damages thereby occasioned;

(b) its agreement that it shall deliver up to the appropriate designated authority the results of any report or any writing as referred to in Section 5(2) hereof.

(2) The rights under this Clause may be exercised without recourse to the Collector or the guarantors specified in Clause 2(6) hereof provided that if any action is instituted against the Collector and or guarantors and any sums recovered in respect of the breach, the said sums shall be set-off from the sums payable by the government of his country/sponsor organisation.

Product
any
5

(3) The Government of Malaysia shall certify in writing, to the Collector its acceptance of the authenticity of the endorsement referred to in sub-clause (1) hereof.

(4) The consent referred to in sub-clause (1) hereof and its certification referred to in (3) hereof shall be conditions precedent to the validity of this agreement.

9. (1) No patent application shall be filed within or outside the country in respect of the collected specimens or any part thereof its properties or activity or any derivatives which utilise the knowledge of indigenous groups or 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 plant extracts or compositions used by indigenous peoples, or, if the same is the intellectual right of indigenous communities.

The provisions of the CIRA shall govern the said collected specimens, any part thereof, its properties or activity where the specimen is an innovation of the indigenous community as set out by the CIRA.

(2) All licenses granted on any patents arising from this agreement shall contain a clause referring to this agreement and shall indicate that the licensee has been apprised of this agreement.

(3) In the event of the licensing of any marketable product the payments as set out in clauses 6 or 7, whichever is applicable, shall be made.

(4) Such payment terms shall apply equally to instances where the invention is the actual isolated natural product, or where the invention is a product structurally based on the isolated natural product (that is, where the natural product provides the lead for development of the invention) or where the invention is an innovation as defined by the CIRA, unless otherwise agreed to in writing by the parties.

(5) The provisions of this clause shall apply notwithstanding that an organism is freely available from different countries, but a phenotype/genotype producing an active agent from a plant is found only in this country.

10. The collaborators may screen additional samples of the raw materials for other biological activities and develop them for such purposes as they may deem fit (including the patenting thereof) independently of this agreement;

Provided that the right for the collaborators to do so will arise six months after collection of the samples by the collector.

11. The Government shall have the right, in the event of the breach of any of the terms herein and subject to Clause 8(2) hereof, to call upon the Collector and/or the sponsor organisation to show cause why action should not be taken against them for the breach.

Provided always that the Government may proceed against the guarantors without first proceeding against the Collector.

12. This agreement and the rights hereunder shall not be assigned transferred or in any way divested without the consent in writing of the Government and subject always in such event to the assignee or transferee accepting all rights and obligations under this contract and provided that the foreign Government of the Collector's origin duly consents in writing to the said assignment/transfer and confirms that its endorsement of this contract also enures and attaches to the new arrangement.



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Community Intellectual Rights Act

An Act to provide for the establishment of a *sui generis* system in respect of ~~plant varieties~~

~~genetic resources and~~ *biological resources*

Interpretation

In this Act the following terms shall bear the following meanings:

(a) "commercial utilization" occurs when the innovation and any process relating to it or product embodying it is made available for sale in the modern market sector.

(b) "innovator" shall mean the local community responsible for the innovation.

(c) "innovation" shall include any collective and cumulative knowledge or technology of the use, properties, values and processes of any ~~plant variety and any plant~~ or 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 utilise the knowledge of indigenous groups or 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 plant extracts or compositions used by the indigenous people.

(d) "local community" refers to a group of people having a long standing social organisation that binds them together whether in a defined area or howsoever otherwise and shall include indigenous peoples, and local populations, and shall where appropriate refer to any organisation duly registered under the provisions of this Act to represent its interest.

(e) ^{*Biological resources*} ~~"plant variety"~~ shall include a plant species or category of a lower level or any part thereof or germplasm therein whether domesticated or not used in accordance with established customs practices laws by local communities for a particular purpose that requires a prior knowledge of a particular property of the plant such as food, medicine and dye.

(f) the "State" shall refer to the appropriate government ministries or the government as a whole where the context so admits.

1. Custodianship

1.1 The local community shall at all times and in perpetuity be the lawful and sole custodians and stewards of an innovation.

1.2 No innovation shall be sold assigned transferred or dealt with in any way whereby the status of the local community as custodians and stewards of the innovation is impaired.

2. Free exchange amongst communities

2.1 There shall be ^{according to} free access to, and the local communities shall make available, its innovation and practices in relation thereof to other communities wherever situate without any payment or reward provided always that such innovation is not acquired for commercial utilisation.

2.2 Such acquirer shall make the said innovation available to any other community on the same basis and terms as set out in section 3.1 hereof.

3. Use for Commercial purposes

3.1 Any person, body, organisation or corporation using any innovation or any part thereof for commercial utilisation shall pay to the local community which is the custodian or steward of the said innovation a sum representing not less than ___ per centum of the gross sales of any product or process incorporating the said innovation.

3.2 Any local community may opt to be paid a non-monetary equivalent as may be determined by the local community in accordance with its customs, practices and usages.

3.3 Nothing in this section shall prevent more than one person, body, organisation or corporation from using any innovation or any part thereof for commercial utilisation and at the same or any other time.

3.4 The payment shall be made:

- (a) to an organisation duly registered under the provisions of this Act as representing the local communities
- (b) where no such organisation exists, to the State which shall hold it in trust for the local community pending its registration under the provisions of this Act
- (c) in respect of an innovation which is, as at the date of the coming into force of this Act, developed by any community, to the State which shall then apply any such monies for the protection, development and maintenance of its genetic resources.

3.5 All monies or their equivalent received by the local community or the State as its trustee shall be applied for such

purpose as the local community may decide including but not limited to the protection, development and maintenance of its genetic resource.

4. Registration of local community

4.1 Any local community may apply to be registered as an organisation to represent its interests provided that its failure to do so will not prejudice its status as custodian or stewards of its innovation under Section 1.1 hereof.

4.2 Registration shall be affected by the duly authorised representative of the local community attending at the Registry set up under this Act and providing and completing particulars as set out in Form 1.

4.3 The Community may change the particulars by attending at the Registry and filing Form II.

5. The Registry of Invention (ROI)

The Community may register its innovation in the ROI provided always that non-registration will not mean that the community was/is not the custodian or steward of the invention under the innovation under Clause 1 hereof.

6. Proof of Invention

6.1 Upon the duly constituted representatives of the Community declaring in a form or manner valid by their laws, customs or practices that they have been using and are the custodians or stewards of an innovation, the innovation shall be deemed to vest in the Community.

6.2 Anyone wishing to challenge this will bear the legal and evidentiary burden of proof for doing so.

7. Technical Institution

There shall be nominated by the State in consultation ^{and consent} with the communities, technical institutions to assist the community to identify and characterise their innovation.

8. Co-ownership

8.1 Nothing in this Act shall prevent any other community or Communities wherever situate from establishing their rights to the custodianship or stewardship of an innovation.

8.2 In such event, the community shall be co-stewards or custodians of the innovation.

8.3 The co-stewardship will carry with it the same rights, duties, and obligations as hereinbefore set out save that they shall be co-terminous and enjoyed together with the co-stewards or custodians.

8.4 All benefits that accrue to one co-steward shall enure to the benefit of the other co-steward or co-stewards.

8.5 Each co-steward shall hold in trust all rights, obligations, rewards, remuneration etc. for the other co-steward or co-stewards.

9. Right to enforce, monitor or further the innovation

9.1 Any State, non-governmental organisation or the local community and/or its duly registered organisation shall have the locus to enforce, monitor and further the local community's innovation and any matters in relation to its utilisation, exchange or impairment, whether in Court or elsewhere provided always that the duly registered organisation of the local community shall take precedence and that the local community shall be informed at every stage of the progress of the same.

The States become custodians of communities

Again, // with Brazilian ^{indigenous} land tenure law from the bottom up.