WIPO/ECTK/SOF/01/3.10

ORIGINAL: English DATE: May 2001





INTERNATIONAL CONFERENCE ON INTELLECTUAL PROPERTY, THE INTERNET, ELECTRONIC COMMERCE AND TRADITIONAL KNOWLEDGE

organized
under the auspices of
His Excellency Mr. Petar Stoyanov, President of the Republic of Bulgaria

by the World Intellectual Property Organization (WIPO)

in cooperation with the National Intellectual Property Association of Bulgaria

Boyana Government Residence Sofia, May 29 to 31, 2001

INTELLECTUAL PROPERTY, TRADITIONAL KNOWLEDGE AND GENETIC RESOURCES

INTELLECTUAL PROPERTY ASPECTS OF TRADITIONAL AGRICULTURAL KNOWLEDGE

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This paper is an extract from a more comprehensive document, which will be published and presented by Professor Blakeney later in 2001.

THIS PAPER WAS SENT AS A CONTRIBUTION TO THE CONFERENCE PROGRAM BY

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ABSTRACT

1. The role of the traditional knowledge of indigenous peoples in the development of pharmaceutical products has been the subject of considerable discussion in recent years. This discussion has involved a consideration of the possibility of intellectual property protection for traditional knowledge and the extent to which this knowledge in facilitating the access to genetic resources, should be the subject of benefit sharing under the Convention on Biological Diversity (CBD). Less widely discussed has been the role of traditional knowledge in the identification of crop types and in the development of new crop varieties. This paper examines the significance of traditional knowledge for agricultural innovations and the possibilities for the protection of this knowledge within the context of the CBD and the WTO agreement on Trade Related Aspects of Intellectual Property Rights and the various national implementations of these international obligations. Finally, the paper considers the possibilities for the protection of traditional agricultural knowledge within the context of the International Undertaking on Plant Genetic Resources.

ROLE OF INDIGENOUS AND TRADITIONAL COMMUNITIES IN BIODIVERSITY CONSERVATION AND INNOVATION

- 2. The traditional knowledge of indigenous peoples throughout the world has played an important role in identifying biological resources worthy of commercial exploitation. For example, the search for new pharmaceuticals from naturally occurring biological material has been guided by ethnobiological data¹. The recent passion for environmental sensitivity in Western countries has resulted in a heightened interest in natural products. Research into these products has been guided by the knowledge of Indigenous Peoples. In 1991, Merck, a multinational pharmaceutical company, entered into a bioprospecting agreement with the Costa Rican Association Instituto Nacional de Biodiversidad (INBio) a non-profit organisation. Under the agreement, over a two-year period, Merck received 10,000 plant samples². The samples were supplied with information about their traditional use. Merck has paid a reported US\$1.35 million for the 10,000 samples, and has agreed to pay a royalty of between 2% - 3%³. Currently, three of the drugs that Merck sells earn over US\$1 billion each. If one of the 10,000 samples becomes a billion dollar drug then Merck has agreed to pay 20 - 30 million dollars in royalties. Conceivably, the royalties from the 10,000 samples could earn Costa Rica well in excess of US\$100 million per annum. This is clear evidence of the commercial value which the pharmaceutical industry places on indigenous peoples intellectual property. In 1995 the estimated market value of pharmaceutical derivatives from indigenous peoples traditional medicine is US\$43 billion⁴ worldwide. Under current intellectual property law, there is no obligation for companies which utilize the traditional knowledge of indigenous peoples to provide any compensation to recognise their equity in the commercial application of this knowledge.
- 3. A similarly significant contribution has been made by the knowledge of indigenous peoples and traditional farmers in the development of new crop types and biodiversity conservation. These groups have been an important agency in the conservation of plant genetic resources and the transmission of these resources to seed companies, plant breeders and research institutions. They have not typically been paid for the value they have delivered, whereas breeders and seed companies have resorted to intellectual property rights to recover their development expenditures. On the other hand, farmers who utilize improved varieties are obliged to pay for them.

- 4. The economic value of biological diversity conserved by traditional farmers for agriculture is difficult to quantify.⁵ It has recently been suggested that "the value of farmers' varieties is not directly dependent on their current use in conventional breeding, since the gene flow from landraces to privately marketed cultivars of major crops is very modest" because "conventional breeding increasingly focuses on crosses among elite materials from the breeders own collections and advanced lines developed in public institutions." On the other hand, those collections and advanced breeding lines are often derived from germplasm contributed by traditional groups.
- 5. An increasingly significant economic value of biodiversity is the extent to which it provides a reservoir of species available for domestication, as well as genetic resources available for the enhancement of domestic species. The modern biotechnological revolution has enabled the engineering of desirable genetic traits from useful local species. For example, bacterial blight resistance in rice has been derived from an otherwise low yielding strain of rice indigenous to Mali, similarly the susceptibility of cultivated sugar cane to mosaic virus was overcome by the introduction of the resistance of wild relatives. It is estimated that about 6.5% of all genetic research undertaken in agriculture is focussed upon germplasm derived from wild species and land races.

THE CONVENTION ON BIOLOGICAL DIVERSITY (CBD)

- The Rio Earth Summit, which was convened in June 1992, promulgated the 6. Convention on Biological Diversity (CBD), The Rio Declaration on Environment and Development and Agenda 21. The CBD represented an attempt to establish an international programme for the conservation and utilization of the world's biological resources⁹ and for the "fair and equitable sharing" of the benefits arising from the utilisation of genetic resources¹⁰. "The single most divisive issue in the negotiations was the relationship between intellectual property rights and access to genetic resources"11. The developing countries of the South, generally speaking the most with substantial source of genetic resources, sought to use the CBD as a means of bargaining access to those resources for royalties, technology and research data. Thus the CBD contains articles on access to genetic resources (Art. 15); access to and the transfer of technology (Art. 16); informed consent and the distribution of benefits of biotechnological innovations (Art. 19). The industrialised group of countries, obviously the principal source of biotechnological innovation, insisted that the CBD did not conflict with intellectual property rights. Thus for example, Art. 16 (2) contains the statement that "In the case of technology subject to patents and other intellectual property rights, such access and transfer shall be provided on terms which recognize and are consistent with the adequate and effective protection of intellectual property rights."
- 7. Reflecting the uncomfortable political deal which was struck in bringing the CBD to conclusion, the language of the Convention is unfortunately vague. The positive affirmation of principles in a number of areas is qualified by vague transcendental values. Thus the respect for intellectual property affirmed by Art. 16 (2) is counterbalanced by the phrase in the same provision that "access to and the transfer of technology...shall be provided and/or facilitated under fair and most favourable terms...". Similarly, Art. 15 (4) provides that

"access [to genetic resources] where granted shall be upon mutually agreed terms." Art. 19(2) provides that "access ... to the results and benefits arising from biotechnologies...shall be on mutually agreed terms". Since mutuality is a precondition for an agreement of any sort, these provisions may be mere rhetoric. On the other hand, they may be a guarantee against unilateral expropriation.

SCOPE OF THE CBD ACCESS REGIME

- 8. Article 1 of the CBD envisages "appropriate access to genetic resources" and "the fair and equitable sharing of benefits arising out of the utilization of genetic resources." "Genetic resources" are defined in Art. 2 as meaning "genetic material of actual or potential value". The term "genetic material" is then defined in Art. 2 to mean "any material of plant, animal, microbiological or other origin containing functional units of heredity". On a strict analysis of this definition, it is suggested that biochemical extracts which do not contain DNA or RNA would be outside the scope of the CBD. 12 Thus the Convention would apply to seeds and cuttings and DNA extracted from a plant, such as a chromosome, gene, plasmid or any part of these such as the promoter part of a gene. 13
- 9. Article 9 deals with "the conservation of components of biological diversity outside their natural habitats", for example, in germplasm and seed banks, botanical gardens, museums, laboratories and agricultural research institutions. This article calls for national legislation to provide for the acquisition, conservation, storage and management of these *ex situ* collections. The access and benefit-sharing provisions of the CBD do not apply to the genetic resources of a country which were collected prior to the entry of the CBD into force in that country. ¹⁴ Thus a country with a pre-existing collection of genetic material has the sovereign right to control access to that collection, but has no legal right to insist upon a share of any benefits derived from the use of that collection. Also, the CBD applies to those genetic resources which originate in the country of a contracting party. ¹⁵

SOVEREIGN RIGHTS OVER GENETIC RESOURCES (ART 15 (1))

Article 15 (1) of the CBD affirms "the sovereign rights of States over their natural resources" and provides that "the authority to determine access to genetic resources rests with the national governments and is subject to national legislation". This provision, dealing as it does with access to genetic resources, does not refer to the question of the ownership of genetic resources. These resources may be of two types: ex situ, in that they are preserved outside their natural habitats, in for example gene banks; or *in* situ, where genetic resources exist within ecosystems and natural habitats or, where domesticated or cultivated, they exist in their agricultural surroundings. Different ownership regimes may apply to these two categories of genetic resources. In recent years difficult questions have been raised concerning the legal status of the germplasm collections of the agricultural research institutes which are members of the CGIAR. A number of the research institutes which make up the CGIAR were established in the 1960s and 70s as a means of precipitating what became known as the "Green Revolution". At that time the questions of ownership and intellectual property rights in the collections were very much subordinated to the mission to increase crop yields to feed a burgeoning world population. It has only been in recent years that ownership issues have become important, either as a bargaining counter in North-South negotiations or as a source of revenue. 16

- 11. The question of the ownership of the CGIAR collections issue arises in two principal contexts. First, the status of the collection upon the dissolution of the relevant gene bank and, secondly, the related question of the authority of the centres to permit third parties to exploit their genetic resources. The starting place for these inquiries commences with an analysis of the legal status of these institutes themselves. The legal status of these collections has always been problematic. In 1986 the FAO had conducted a review of the legal status of all national and international institutions operating genebanks¹⁷. In relation to the CGIAR centres, the FAO report concluded that as control over their operation was shared between national and international representatives, they were not international in the strict sense, as they were not created by any international instrument or organization. On the other hand the report concluded that because they were not either in the private sector or under the control of any State or national authority, the CGIAR centres were *sui generis*. Consequently, the report reached no firm conclusion on the ownership of the genetic resources controlled by the Centres.
- For example, ownership concerns were raised recently as a consequence of Plant Breeder's Rights applications made in Australia by agricultural research institutes in relation to a peavine and a lentil which had been bred from genetic stock obtained from the CGIAR gene bank: International Centre for Agricultural Research in the Dry Areas (ICARDA), located in Aleppo, Syria¹⁸. A charter for ICARDA had been established in November 1975 on the basis of an agreement between the World Bank, FAO and UNDP and the Canadian International Development Research Centre (IDRC), as the executing agency. Subsequently establishment agreements were negotiated by IDRC with Syria (28 June 1976), Lebanon (6 July 1977) and Iran (20 July 1976). These parallel agreements provide for the establishment of ICARDA in "the region" defined as the "Near East, North Africa and the Mediterranean region". ICARDA's headquarters were established in Aleppo, Syria. The agreements also provided for the Chairman of CGIAR to declare that ICARDA has been established as a legal entity allowing IDRC's role to lapse. This formal step does not appear to have been taken. The question of ownership of the ICARDA collection was raised in the context of whether its Director-General acted in breach of trust obligations, which he owed in relation to ICARDA genetic material, in permitting the Australian agricultural research institutes to seek intellectual property rights in applications of that material¹⁹.
- 13. An aspect of the germplasm ownership issue, which was illustrated by the Australian dispute, is that the farmers and the countries of the South were perceived as the victims of biopiracy perpetrated by corporations of the North. In 1998, in response to concerns about unauthorised third parties securing intellectual property rights in relation to its germplasm, called for a moratorium on the granting of IPRs on all plant germplasm held in trust under the FAO's auspices. In the same year, the International Service for National Agriculture Research (ISNAR), which is operated by the CGIAR, commissioned a report on the use of proprietary technologies by CGIAR Centers. Following the observations made by this report, each of the CGIAR Centres, commissioned audits of their intellectual property management policies and ISNAR established a Central Advisory Service to provide legal counsel on intellectual property rights.
- 14. As is discussed below, one impact of intellectual property issues upon the CGIAR has been calls for the limitation of the availability of intellectual property rights in relation to plant genetic resources. Another approach has been to embrace the new legal reality. Some CGIAR Centres perceive that CGIAR-generated intellectual property might be used as a bargaining chip, to be traded for biological tools patented by the private sector. For example the *Policy on Intellectual Property* of the International Maize and Wheat Improvement Center

(CIMMYT) envisages that intellectual property protection may be sought "to facilitate the negotiation and conclusion of agreements for access to proprietary technologies of use to CIMMYT's research and in furtherance of its mission²². This proprietisation of public sector agriculture research is questioned, particularly by those NGO's opposed to patenting in the life sciences²³.

15. An issue which has not yet been addressed by the CGIAR of the FAO is the question of the rights, if any, of the indigenous and traditional communities from which seeds might have been collected by the various CGIAR institutes. That collection may have been informed by the knowledge of those communities, or may have occurred without the communication by the collector to those communities of the implications of the act of collection.

MUTUALLY AGREED TERMS, PRIOR INFORMED CONSENT AND BENEFIT SHARING

- 16. Article 15 (4) of the CBD envisages that where access is granted it will be subject to mutually agreed terms. Currently the conventional form of access agreement is the Material Transfer Agreement (MTA). A number of the provisions of the CBD refer to the equitable sharing of benefits arising from the utilisation of the genetic resources of a signatory. Article 15 (7) requires each Contracting Party to "take legislative, administrative or policy measures, as appropriate" and in accordance with a number of specified provisions of the Convention, "with the aim of sharing in a fair and equitable way, the results of research and development and the benefits arising from the commercial and other utilization of genetic resources with the Contracting Party providing such resources". Article 8(j) envisages the "equitable sharing" of benefits with indigenous and local communities, arising out of the use of the traditional knowledge, innovations and practices of those communities. Article 21 provides for the establishment of a "mechanism" for the provision of financial resources to developing country parties to the CBD.
- 17. Complementary to the equitable sharing of benefits, the CBD provides for the access of developing country signatories to technologies which may result from the utilisation of the genetic resources which they may provide. Article 16 (1) recites the importance of access to biotechnologies to attain the objectives of the CBD and Art 16 (2) provides for the access to technologies by developing countries on "fair and equitable terms, including on concessional and preferential terms". Article 19 (1) requires parties to take appropriate measures to "provide for the effective participation in biotechnological research activities by those Contracting Parties, especially developing countries, which provide the genetic resources for such research". Article 19 (2) requires parties to "take all practicable measures to promote and advance priority access on a fair and equitable basis ..., especially developing countries, to the results and benefits arising from biotechnologies based upon genetic resources provided by those Contacting Parties" on mutually agreed terms.

INDIGENOUS AND LOCAL COMMUNITIES

18. The Rio Declaration in Principle 22 stated that 'Indigenous peoples and their communities ... have a vital role in environmental management and development because of their knowledge and traditional practices'. Chapter 26 of Agenda 21 detailed the relationship which conference participants recognised between indigenous peoples and their lands. The Agenda, at para. 26.3(a), required governments:

...to establish a process to empower indigenous peoples and their communities' through measures that include:

- recognition of their values, traditional knowledge and resource management practices with a view to promoting environmentally sound and sustainable development;
- enhancement of capacity- building for indigenous communities based on the adaptation and exchange of traditional experience, knowledge and resource-management practices, to ensure their sustainable development;
- establishment, where appropriate, of arrangements to strengthen the active participation of indigenous peoples and their communities in the national formulation of policies, laws and programs relating to resource management and other development processes that may affect them.
- 19. The Preamble to the CBD recognised the ... close and traditional dependence of many Indigenous and local communities embodying traditional lifestyles on biological resources, and the desirability of sharing equitably arising from the use of traditional knowledge, innovations and practices relevant to the conservation of biological diversity and sustainable use of its components.
- 20. Article 8(j) of the Convention required each signatory ... subject to its national legislation, respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity and promote their wider application with the approval and involvement of the holders of such knowledge, innovations and practices and encourage the equitable sharing of the benefits arising from the utilization of such knowledge, innovations and practices.
- 21. The provisions of Art. 8(j) require implementation through national legislation. It is expressed to be subject to national legislation, in order to preserve legislation on this subject which predates the CBD.²⁵

FARMERS' RIGHTS

- 22. In 1983 the Conference of the FAO adopted the International Undertaking on Plant Genetic Resources (IUPGR) as a non-legally binding instrument. The IUPGR provides for the exploration and collection of genetic resources (Art. 3), for conservation *in situ* and *ex situ* (Art. 4), for the availability of plant genetic resources (Art. 5), for international cooperation in conservation, exchange and plant breeding (Art. 6), for international coordination of genebank collections and information systems (Art. 7) and for funding (Art. 8). Some 113 countries have subscribed to the IUPGR, excluding the USA²⁶.
- 23. The IUPGR was originally predicated on the principle that plant genetic resources should be freely exchanged as a "heritage of mankind" and should be preserved through international conservation efforts. In subsequent years the principle of free exchange was gradually narrowed. In November 1989 the 25th Session of the FAO Conference adopted two resolutions providing an "agreed interpretation" that plant breeders' rights were not incompatible with the IUPGR²⁷. The acknowledgment of plant variety rights obviously benefited industrialised countries, which were active in seed production. In exchange for this

concession, developing countries won endorsement of the concept of "farmers' rights". This was a moral commitment by the industrialised commitment to reward "the past present and future contributions of farmers in conserving, improving and making available plant genetic resources particularly those in centres of origin/diversity. Farmers' Rights were defined in a Resolution of the 1989 FAO Conference²⁸ as ... rights arising from the past, present and future contribution of farmers in conserving, improving and making available plant genetic resources, particularly those in centres of origin/diversity. These rights are vested in the International Community, as trustee for present and future generations of farmers, for the purpose of ensuring full benefits to farmers, and supporting the continuation of their contributions.

- 24. Farmers' rights were intended to promote a more equitable relation between the providers and users of germplasm by creating a basis for farmers to share in the benefits derived from the germplasm which they had developed and conserved over time.²⁹ An International Fund for Plant Genetic Resources was proposed in a Resolution of 1991 as a means of implementing Farmers' Rights. This Fund will support plant genetic conservation and utilization programmes, particularly in the developing countries.
- 25. Farmers' rights are conceived of as a "retrospective equity,"³⁰ primarily as the recognition of the moral obligation, rather than an economic incentive. Its implementation is uncertain, although suggestions have been made in India for a seed tax, where the revenue yield will be distributed through a Community Gene Fund.³¹
- 26. At its Eighth session in 1999 the members of CGRFA agreed the following article:

Article 15 – Farmers' Rights

- 15.1 The Parties recognize the enormous contribution that the local and indigenous communities and farmers of all regions of the world, particularly those in the centres of origin and crop diversity, have made and will continue to make for the conservation and development of plant genetic resources which constitute the basis of food and agriculture production throughout the world.
- 15.2 The Parties agree that the responsibility for realizing Farmers' Rights, as they relate to Plant Genetic Resources for Food and Agriculture, rests with national governments. In accordance with their needs and priorities, each Party should, as appropriate, and subject to its national legislation, take measures to protect and promote Farmers' Rights, including:
 - (a) protection of traditional knowledge relevant to plant genetic resources for food and agriculture;
 - (b) the right to equitably participate in sharing benefits arising from the utilization of plant genetic resources for food and agriculture;
 - (c) the right to participate in making decisions, at the national level, on matters related to the conservation and sustainable use of plant genetic resources for food and agriculture.

15.3 Nothing in this Article shall be interpreted to limit any rights that farmers have to save, use, exchange and sell farm-saved seed/propagating material, subject to national law and as appropriate.

WTO AGREEMENT ON TRADE RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS (TRIPS)

- Paralleling the formulation of the Convention on Biological Diversity, were the negotiations of the Uruguay Round of the General Agreement on Tariffs and Trade. Attempts by the World Intellectual Property Organization to revise the Paris Convention on Industrial Property, 1883, which deals with the international patents, industrial designs and trade marks regime, had foundered on the irreconcilability of the position of developing countries and industrialised countries on the compulsory licensing of patents.³². For this and other reasons, the US proposed that the GATT formulate legislative norms for intellectual property protection and that it require the introduction of a range of mechanisms for the enforcement of intellectual property rights³³. The resultant Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) was annexed as a condition of membership to the Agreement Establishing the World Trade Organization (WTO)³⁴. Article 27.3 of the TRIPS Agreement permits signatories to exclude from patentability "plants and animals other than microorganisms, and essentially biological processes for the production of plants or animals, other than non-biological and microbiological processes". However, the provision requires that "Members shall provide for the protection of plant varieties either by patents or by an effective sui generis system or by any combination thereof". Article 65.2 permits developing countries a period of five years for compliance with TRIPS commencing from the date of entry into force of the WTO Agreement, in April 1994. Least developed countries are permitted an additional five years for the implementation of TRIPS "bio-piracy" controversies, involving patent applications in relation to genetic material obtained from a number of developing countries³⁵.
- 28. There is a vigorous debate on the sorts of *sui generis* systems which might comply with Art. 27.3(b). The TRIPS provision makes no reference to the International Convention for the Protection of Plant Varieties (UPOV). This is considered to provide some leeway in the formulation of *sui generis* systems.³⁶ Furthermore, key elements for the shaping of *sui generis* systems are either unclear or not defined. First, there could be several ways to define the term plant variety. For granting protection under the traditional plant breeders right (PBR) system, plant varieties must meet the criteria of being distinct, uniform and stable (DUS). It has been suggested that "Uniformity" and "stability" could be replaced by the criterion of identifiability, allowing the inclusion of plant populations which are more heterogeneous, thus taking into account the interests of local communities³⁷. The scope of protection could be limited to cover only the reproductive parts of plants, or could be extended to include also harvested plant materials.
- 29. Secondly, the TRIPS Agreement does not prohibit the development of additional protection systems, nor does it prohibit the protection of additional subject matter to safeguard local knowledge systems and informal innovations as well as to prevent their illegal appropriation.
- 30. The original formulation and promulgation of the TRIPS Agreement had occurred largely without the active participation of developing countries. Their principal negotiating

position during the Uruguay Round had been to question the relevance of intellectual property for the GATT, particularly as WIPO had already been established as the United Nations' specialized agency for intellectual property matters. The failure of developing countries to address the substance of TRIPS during the Uruguay Round was sought to be remedied by their active participation in the review procedure. The various regional groupings of developing countries held meetings to agree a common negotiating position for the TRIPS and also the CBD reviews. Typical of these was the meeting of the Non-Aligned and Developing Countries at New Delhi on 29-31 January 1999.

- 31. The New Delhi meeting issued a Perambular Statement in which concern was expressed that the TRIPS Agreement failed to address the central objectives of the CBD, in particular the questions of access to genetic resources and the equitable sharing of benefits. The Statement also called for a regime to protect local and community knowledge and the knowledge systems of indigenous peoples. The expansion of, or at the very least, the maintenance of the exceptions in Art. 27.3(b) of TRIPS for the patenting of life forms was urged. The expansion was sought to extend to "micro-organisms, products and processes thereof." The definition of micro-organism was sought to be expanded to cover tissues, cells or cell-lines or DNA obtained from higher organisms, including human beings." The New Delhi meeting sought the expansion of the *sui generis* clause to:
 - (i) ensure implementation of Art. 8(j) of the CBD relating to indigenous and local communities:
 - (ii) ensure that full consideration of environmental and ethical concerns about IPRs on life forma are addressed:
 - (iii) allow the completion of a biosafety protocol that establishes minimum international standards for the environmental safety of releases of genetically modified organisms.
- 32. The meeting sought the removal of the word "effective" from Art. 27.3(b) or by defining it such that national priority is paramount in the interpretation of the term, including:
 - (i) conservation and sustainable use of biodiversity;
 - (ii) promotion of traditional lifestyles;
 - (iii) promotion of food and health security;
 - (iv) ensuring equitable benefit sharing;
 - (v) invoking the precautionary principle;
 - (vi) respecting the principles of equity and ethics.
- 33. The meeting recommended the insertion in Art. 29, concerned with patenting, a specific requirement obliging the disclosure "of the genetic resources and the traditional knowledge used in inventions for which IPRs are claimed, the country and community of origin of these resources and knowledge and proof of consent having been sought of the relevant community and equitable benefit-sharing arrangements having been entered into with them, as required by the CBD."
- 34. Parallel recommendations were made in relation to the review of the CBD. Thus in relation to the access and benefit sharing provisions of the CBD, the New Delhi meeting urged: the "consideration of mechanisms such as certificates of origin, evidence of prior consent for access to genetic resources, evidence of prior approval of indigenous and local communities for access to traditional knowledge, and disclosure of this evidence in patent

applications". Similar provisions were urged for the FAO Undertaking on Plant Genetic Resources.

- 35. In relation to national patent legislation in the countries of Southern Asia, the meeting recommended the exclusion from patentability of all life forms, existing traditional/indigenous knowledge and products and processes "essentially derived from that knowledge." It was recommended that patent applications should include:
 - (i) disclosure of all places of origin in the material/knowledge used in the application;
 - (ii) disclosure of all communities/persons of origin;
 - (iii) proof of consent having been obtained from the community/persons of origin;
 - (iv) proof of benefit-sharing arrangement having been entered into with the community/persons of origin ...;
 - (v) disclosure of any previous rejection of application, in the country or other jurisdictions;
 - (vi) prior public notice in all relevant languages in the places or communities of origin.
- 36. The New Delhi meeting rejected the UPOV Convention as an adequate model for *sui generis* plant variety protection. It urged the adoption of alternative models, incorporating the same sort of provisions as it recommended for national patent laws, and recommended the inclusion of a comprehensive code of provisions protecting Farmers' Rights. The establishment of a gene fund, "derived from fees and other levies on plant breeding and the seed industry" was recommended, to be used to support in-situ farmers' conservation. The consideration of new varieties for protection should include "an environmental and social impact assessment to ensure that they do not threaten agro-diversity and community rights".
- 37. The New Delhi meeting also recommended the development of *sui generis* legislation to protect the folklore and traditional medical knowledge of indigenous persons and the compilation of a database, or registry of the knowledge wealth of a country.
- 38. Similar conclusions were reached at meetings held in Africa and Latin America. A *Communication* was made to the WTO from Kenya, on behalf of the African Group, to assist the Preparations for the 1999 Ministerial Conference. The Communication pointed out that as the deadline for implementation of the obligations by developing countries of the TRIPS Agreement was January 2000, the review would precede the implementation of obligations undertaken by developing countries. As developing countries would have had insufficient experience with the operation of the Agreement they would have had no prior opportunity to conduct impact assessment studies of implications resulting therefrom.
- 39. Furthermore, the Communication pointed out that the review would pre-empt the outcome of deliberations in other related for such as CBD, UPOV, FAO, International Undertaking on Plant Genetic Resources, and the development of an OAU model law on Community Rights and Control of Access to Biological Resources. They proposed that an additional five years be allowed, prior to the review of Art. 27.3(b).
- 40. The African group proposed that "after the sentence on plant variety protection in Article 27.3(b), a footnote should be inserted stating that any *sui generis* law for plant variety protection can provide for:

- (i) the protection of the innovations of indigenous and local farming communities in developing countries, consistent with the Convention on Biological Diversity and the International Undertaking on Plant Genetic Resources;
- (ii) the continuation of the traditional farming practices including the right to save, exchange and save seeds, and sell their harvest;
- (iii) preventing anti-competitive rights or practices which will threaten food sovereignty of people in developing countries, as is permitted by Article 31 of the TRIPS Agreement.
- 41. On 25 July 1999 a Federation of Indigenous Peoples groups issued a statement for the purposes of the TRIPS review. The Statement commences with the observation that "Humankind is part of Mother Nature, we have created nothing and so we can in no way claim to be owners of what does not belong to us. But time and again, western legal property regimes have been imposed on us, contradicting our own cosmologies and values." It expresses concern that Article 27.3(b) "will further denigrate and undermine our rights to our cultural and intellectual heritage, our plant, animal, and even human genetic resources and discriminate against our indigenous ways of thinking and behaving."
- 42. The Statement drew the distinction between private proprietorial rights and "Indigenous knowledge and cultural heritage [which] are collectively and accretionally evolved through generations The inherent conflict between these two knowledge systems and the manner in which they are protected and used will cause further disintegration of our communal values and practices.
- 43. The Statement pleaded for a legislative structure which "Builds upon the indigenous methods and customary laws protecting knowledge and heritage and biological resources" and which prevents the appropriation of traditional knowledge and integrates "the principle and practice of prior informed consent, of indigenous peoples' as communities or as collectivities."
- 44. This Statement was picked up by a submission of Cuba, Honduras, Paraguay and Venezuela to the TRIPS Council,³⁹ which stated that these countries "consider it fair to recognize the specific contribution of indigenous and tribal peoples and local communities to the cultural diversity and social and ecological harmony of mankind."
- 45. Responding to these developing country initiatives, the USA has urged that an effective *sui generis* system should clearly identify: (a) the subject matter of protection; (b) any limitations to the rights which will be granted under such a system; and (c) the legal remedies available to rights holders⁴⁰. In relation to a *sui generis* system for the protection of plant varieties, the US submission was that all plant varieties should be covered, with the objective of encouraging the development of new varieties from the widest possible range of genera and species⁴¹. This submission also recommended confining this system of protection only to breeders or others specifically entitled through contract law or succession. The US submission was unsympathetic to the claims of indigenous people for the protection of oral knowledge and practices, because of the inaccessibility of this information beyond the relevant indigenous community⁴².

46. The US submission was hostile to suggestions to facilitate benefit sharing by requiring the identification of the source of genetic materials and traditional knowledge in patent applications. Its preferred approach was to oblige parties to negotiate benefit sharing arrangements as a condition of the grant of access.

WIPO AND ACCESS TO GENETIC RESOURCES

- 47. WIPO's involvement with the issue of access to genetic resources commenced in 1999 with a study, commissioned jointly with the United Nations Environment Programme (UNEP), on the role of intellectual property rights in the sharing of benefits arising from the use of biological resources and associated traditional knowledge. These matters were taken up at the third session of the Standing Committee on the Law of Patents (SCP) in September 1999. The SCP requested the International Bureau to include the issue of protection of biological and genetic resources on the agenda of a Working Group on Biotechnological Inventions, to be convened at WIPO in November 1999. The Working Group, at its meeting, the following month, recommended the establishment of nine projects related to the protection of inventions in the field of biotechnology. The Working Group decided to establish a questionnaire for the purpose of gathering information about the protection of biotechnological inventions, including certain aspects regarding intellectual property and genetic resources, in the Member States of WIPO.
- 48. In response to the invitation issued by the SCP, WIPO organized a Meeting on Intellectual Property and Genetic Resources on April 17 and 18, 2000. The Meeting addressed issues that generally are raised in the context of access to, and *in situ* preservation of, genetic resources in their direct or indirect relationship with intellectual property. The Chairman's Conclusions from the Meeting state that a consensus was reached that "WIPO should facilitate the continuation of consultations among Member States in coordination with the other concerned international organizations, through the conduct of appropriate legal and technical studies, and through the setting up of an appropriate forum within WIPO for future work."
- 49. At the third session of the WIPO Standing Committee on the Law of Patents in September 1999 the delegation of Colombia proposed the introduction into the Patent Law Treaty, proposed as a means of achieving some global harmonization of patent registration procedures, an article which provided that:
 - (i) all industrial protection shall guarantee the protection of the country's biological and genetic heritage. Consequently, the grant of patents or registrations that relate to elements of that heritage shall be subject to their having been acquired made legally;
 - (ii) every document shall specify the registration number of the contract affording access to genetic resources and a copy thereof whereby the products or processes for which protection is sought have been manufactured or developed from genetic resources, or products thereof, of which one of the member countries is the country of origin.
- 50. The Diplomatic Conference, which commenced on May 11, 2000, became bogged down on the question of obliging the identification of source countries in biotechnological patent applications. To facilitate progress on the procedural aspects, the source country

question was referred to an expert group for further consideration. In a press release issued on June 1, 2000, WIPO reported that it had also received a mandate to discuss this issue from the COP 5 meeting in Nairobi and that this request would be referred to its General Assembly in September 2000.

- 51. In a Note dated September 14, 2000, the Permanent Mission of the Dominican Republic to the United Nations in Geneva submitted two documents on behalf of the Group of Countries of Latin America and the Caribbean (GRULAC) as part of the debate on in the WIPO General Assembly on "Matters Concerning Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore." The central thrust of these documents was a request for the creation of a Standing Committee on access to the genetic resources and traditional knowledge of local and indigenous communities. "The work of that Standing Committee would have to be directed towards defining internationally recognized practical methods of securing adequate protection for the intellectual property rights in traditional knowledge."
- 52. The GRULAC documents suggested that questions concerning the use and exploitation of genetic resources and biodiversity and also traditional knowledge, could be divided into two groups depending on whether they are currently recognised or being addressed by intellectual property in the international environment. The first group includes problems whose solutions could in principle be found in known intellectual property regimes. In this group, the preferred remedy would be the broadening or clarification of existing intellectual property remedies.
- 53. It was suggested that the second group comprised those aspects, questions and problems the settlement of which calls for recognition and acceptance of the values and interests whose protection is sought, and the creation of new disciplines and provisions so that their protection may be established at the international level. The GRULAC documents envisaged that the Committee would examine the protection needs and expectations of sectors that possess traditional knowledge and to determine the manner in which they require an adjustment of existing intellectual property regimes or the creation of new ones. The Committee might also consider it necessary to ascertain whether some of the protection claims were not completely outside the present or prospective framework of intellectual property.
- 54. In order to clarify the future application of intellectual property to the use and exploitation of genetic resources and biodiversity and also traditional knowledge, it was suggested that the Committee could clarify: (a) the notions of public domain and private domain; (b) the appropriateness and feasibility of recognizing rights in traditional works and knowledge currently in the public domain, and investigating machinery to limit and control certain kinds of unauthorized exploitation; (c) recognition of collective rights; (d) model provisions and model contracts with which to control the use and exploitation of genetic and biological resources, and machinery for the equitable distribution of profits in the event of a patentable product or process being developed from a given resource embodying the principles of prior informed consent and equitable distribution of profits in connection with the use, development and commercial exploitation of the material transferred and the inventions and technology resulting from it; (e) the protection of undisclosed traditional knowledge.
- 55. Finally, it was suggested that in concert with the secretariat of UPOV, the Committee could embark on the exploration of possible options for defining *sui generis* systems for the protection of genetic resources and biodiversity.

56. At the WIPO General Assembly with the Member States agreed the establishment of an Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore. Three interrelated themes were identified to inform the deliberations of the Committee: intellectual property issues that arise in the context of (i) access to genetic resources and benefit sharing; (ii) protection of traditional knowledge, whether or not associated with those resources; and (iii) the protection of expressions of folklore 45. It was proposed that the Committee would hold its first session in the spring of 2001 and that the next draft Program and Budget would provide for the Committee to meet twice a year in the 2002-2003 biennium. The Committee would report any recommendations for action that it might formulate to the WIPO General Assembly.

See McChesney, 'Biological Diversity, Chemical Diversity and the Search for New Pharmaceuticals' in M. Balick, E. Elisabetsky and S. Laird, eds., *Medicinal Resources of the Tropical Forest: biodiversity and its importance to human health*, Columbia; U.of Columbia Press, 1996, 12.

Indigenous People, Biodiversity, and Health COURTS Canada IPBN Factsheet, Nov 1995.

³ *Ibid*.

⁴ Ibid.

Eg see S.Brush, *Providing Farmers' Rights Through In Situ Conservation of Crop Genetic Resources*, Berkeley, University of California, 1994.

C. Correa, *Options for the Implementation of Farmers' Rights at the National Level*, South Centre, Trade-Related Agenda, Development and Equity "Working Papers, No. 8, December 2000, citing Wright, 'Intellectual Property and Farmers' Rights in R. Evenson, D. Gollin and V. Santaniello, Eds., *Agricultural Values of Plant Genetic Resources*, Wallingford, FAO/CEIS/CABI, 1998, 228.

See Fischer et al, 'Collaborations in rice' (13 October 2000) 290 *Science* 279.

McNeely, 'Biodiversity and Agricultural Development: The Crucial Institutional Issues' in D.R. Lee and C.B. Barrett, Eds, *Tradeoffs or Synergies? Agricultural Intensification, Economic Development and the Environment*, Wallingford, CABI, 2001, 399 at 404.

See F. McConnell, *The Biodiversity Convention. A Negotiating History*, London, The Hague, Boston, Kluwer, 1996.

¹⁰ CBD, Art.1.

Chandler, 'The Biodiversity Convention: Selected Issues of Interest to the International Lawyer', (1993) 4 *Colo. J. Int'l Envl L & Policy* 141 at 161.

See L. Glowka, F. Burhenne-Guilmin and H. Synge *A Guide to the Convention on Biological Diversity*, Gland, IUCN, 1994, 3.

See L. Glowka, A Guide to Designing Legal Frameworks to Determine Access to Genetic Resources, Gland, IUCN, 1998, 4.

CBD, Art. 15(3) and see Yusuf, 'International Law and Sustainable Development: The Convention on Biological Diversity' in A.A. Yusuf, (ed) *African Yearbook of International Law*, vol. 2, The Hague, Boston and London, Kluwer, 1995, 109.

¹⁵ Ibid.

See Blakeney, 'Access to Genetic Resources: The View from the South' [1997] 3 *Bioscience Law Rev.* 97-103.

FAO Commission on Plant Genetic Resources, *Legal Status of Base and Active Collections of Plant Genetic Resources*, Doc. CPGR/87/5, Dec. 1986.

¹⁸ 'Editorial. Lest We Starve', No. 2121, *New Scientist*, 14 February, 1998, 3; Edwards and Anderson, 'Seeds of Wrath', *Ibid*, 14.

See Blakeney, 'Intellectual Property Rights in the Genetic Resources of International Agricultural Research Institutes - Some Recent Problems' [1998] 1 *Bioscience Law Rev.* 3-11.

See Blakeney, 'Access to Genetic Resources: The View from the South' [1997] 3 *Bioscience* Law Rev. 97-103.

²¹ J.Cohen, C. Falconi, J. Komen and M. Blakeney, *The Use of Proprietary Biotechnology* Research Inputs at Selected CGIAR Centers. (The Hague: CGIAR, March 1998).

²² CIMMYT, *Policy on Intellectual Property*, Article III.4.v, www.cimmyt.org/resources/obtaining/seed/ip-policy/htm/ip-policy.htm>.

[Endnote continued from previous page]

- Eg see RAFI, 'In Search of Higher Ground. The Intellectual Property Challenge to Public Agricultural Research and Human Rights and 28 Alternative *Initiatives' The Occasional Paper Series* Vol. 6 No. 1 September 2000.
- See J.I. Cohen, C. Falconi, J. Komen and M. Blakeney, *The Use of Proprietary Biotechnology Research Inputs at Selected CGIAR Centres*, International Service for National Agricultural Research (ISNAR), The Hague, 1998.
- See Chandler, 'The Biodiversity Convention: Selected Issues of Interest to the International Lawyer' (1993) 4 *Colorado Jnl of Int'l Law and Policy* 141.
- FAO, 'Global Participation in the Development of Major Components of the Global System for the Conservation and Utilization of Plant Genetic resources' (September 1996), http://193.43.36.7/waice...GP/AGPS/PGR/globapp1.htm.
- Resolutions 4/89 and 5/89 adopted by FAO Conference, 25th Sess., Rome, 11-29 Nov.1989.
- Annex II, Resolution 5/89 adopted by FAO Conference, 25th Sess., Rome, 11-29 Nov. 1989.
- ²⁹ Glowka, n. 19 *supra*, 6.
- Brush, 'Whose knowledge, whose genes, whose rights?', in S.B. Brush, and D. Stabinsky (eds), *Valuing Indigenous Knowledge: Indigenous Peoples and Intellectual Property Rights*, Washington: DC, Island Press, 12.
- M.S. Swaminathan and V. Hoon, *Methodologies for Recognizing the Role of Informed Innovation in the Conservation and Utilization of Plant Genetic Resources*, Madras, CRSARD Proceedings, no. 9, 1994.
- See M. Blakeney, Legal Aspects f the Transfer of Technology to Developing Countries, Oxford: E SC, 1989. 98ff.
- See Blakeney, 'Intellectual Property in World Trade' [1995] 1 *Int'l Trade Law & Regulation* 76.
- See M. Blakeney, *Trade Related Aspects of Intellectual Property Rights: A Concise Guide to the TRIPS Agreement*, London Sweet & Maxwell, 1996.
- See G. Dutfield, *Intellectual Property Rights, Trade and Biodiversity* (London: Earthscan, 2000)
- Eg see 'Various Systems for Sui Generis Rights Systems' (1998) No. 38 *Biotechnology and Development Monitor* 3.
- Seiler, 'Sui Generis Systems: Obligations and options for developing countries.' Biotechnology and Development Monitor, (1998) No. 34, *Biotechnology and Development Monitor* 2.
- The European Patent Convention was suggested as a precedent for this legislation.
- Proposal on the Protection of the Intellectual Property Rights of the Traditional Knowledge of Local and Indigenous Communities, WT/GC/W/362, 12 October 1999.
- 'Review of the Provisions of Article 27.3(B). Further Views of the United States of America', WTO Doc. IP/C/W/209, 20 September 2000.
- 41 *Ibid.*, 2-3.
- ⁴² *Ibid.*, 5.
- 43 WIPO Doc. WO/GA/26/9
- 44 *Ibid.*, Annex I, 10.
- See WIPO, 'Matters Concerning Intellectual Property Genetic Resources Traditional Knowledge and Folklore', WIPO Doc, WO/GA/26/6, August 25, 2000.

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