



UiTM LAW REVIEW

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INTELLECTUAL PROPERTY, TRADITIONAL KNOWLEDGE AND GENETIC RESOURCES

by MICHAEL BLAKENEY*

Introduction

Article 19 of the November 2001 Doha Declaration instructed the Council for TRIPS (Agreement on Trade-Related Aspects of Intellectual Property Rights 1994), in pursuing its work programme concerning both its review of Article 27.3(b) and its general review of the implementation of the TRIPS Agreement under Article 71.1, “to examine, *inter alia*, the relationship between the TRIPS Agreement and the Convention on Biological Diversity, the protection of traditional knowledge and folklore, and other relevant new developments raised by Members pursuant to Article 71.1”.

To appreciate the scope of this review, it will be useful to trace the evolution of the concept of traditional knowledge as a category of intellectual property right and to examine the proposals which are being developed to give practical effect to the recognition of this right. The relationship between genetic resources and traditional knowledge will also be outlined.

Traditional Knowledge and the Convention on Biological Diversity (CBD)

The Convention on Biological Diversity, which was promulgated at the Rio Earth Summit in June 1992, represented an attempt to establish an international programme for the conservation and utilisation of the world’s biological resources¹ and for the “fair and equitable sharing” of the benefits arising from the utilisation of genetic resources.² 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”. Article 15(4) of the CBD envisages that where access is granted it will be subject to mutually agreed terms. 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 utilisation of genetic resources with the Contracting

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1 See F McConnell, *The Biodiversity Convention. A Negotiating History* (Kluwer London 1996).

2 CBD, Art 1.

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.

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 Article 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 Contracting Parties" on mutually agreed terms.

Decision V/16 of the Fifth Conference of the Parties to the Convention on Biological Diversity (COP 5), held in Nairobi from 15 to 26 May 2000, "[r]equests Parties to support the development of registers of traditional knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant to the conservation and sustainable use of biological diversity.

Traditional Knowledge and the World Trade Organisation (WTO)

A particular contemporary impetus for the formulation of an international positions on the protection of traditional knowledge has been the current debate concerning the review of Article 27.3(b) of the plant variety provision of the TRIPS Agreement.³ Review of this provision was mandated by the TRIPS Agreement itself, to be completed by the end of 1999. Developing country participants in the review process have suggested the importation into the TRIPS Agreement of the provisions in the Convention on Biological Diversity, which provide for equitable sharing with indigenous peoples of the benefits of the utilisation of traditional medical knowledge.⁴ The African Group of Countries proposed the inclusion of this issue in the Ministerial Conference to set the agenda for the Seattle Round of the WTO.⁵ On 25 July 1999, a Federation of Indigenous Peoples Groups issued a statement for the purposes of the review, pleading for a legislative structure which "builds upon the indigenous methods and customary laws protecting knowledge and heritage and biological resources" and which prevents the

3 See M Blakeney, 'International Framework of Access to Plant Genetic Resources' in M Blakeney, *Intellectual Property Aspects of Ethnobiology* (Sweet & Maxwell London 1999) at 1.

4 See M Blakeney, "Biotechnology, TRIPS and the Convention on Biological Diversity" [1998/1999] 4 Bio-Science Law Rev 144-150.

5 Communication to the WTO from Kenya, on behalf of the African Group, WT/GC/W/3026, August 1999. Trade Organisation, WT/GC/W/362 12 October 1999.

appropriation of traditional knowledge and integrates “the principle and practice of prior informed consent of indigenous peoples as communities or as collectivities”. The Statement concluded with an affirmation of the commitment of Indigenous Peoples “to sustain our struggle to have our rights to our intellectual and cultural heritage and our lands and resources promoted and protected”.

On 4 October 1999, Bolivia, Columbia, Ecuador, Nicaragua and Peru specifically proposed that the Seattle Ministerial Conference establish within the framework of the Round a mandate:

- (a) To carry out studies, in collaboration with other relevant international organisations in order to make recommendations on the most appropriate means of recognizing and protecting traditional knowledge as the subject matter of intellectual property rights.
- (b) On the basis of the above-mentioned recommendations, initiate negotiations with a view to establishing a multilateral legal framework that will grant effective protection to the expressions and manifestations of traditional knowledge.
- (c) To complete the legal framework envisaged in paragraph (b) above in time for it to be included as part of the results of this round of trade negotiations.⁶

A communication of 6 August 1999 from Venezuela proposed that the Seattle Ministerial Conference should consider the establishment “on a mandatory basis within the TRIPS Agreement a system for the protection of intellectual property, with an ethical and economic content, applicable to the traditional knowledge of local and indigenous communities, together with recognition of the need to define the rights of collective holders”.⁷

A practical proposal for the integration of traditional knowledge with intellectual property rights is India’s suggestion that material transfer agreements be required where an inventor wishes to use biological material identified by traditional knowledge. That obligation would be incorporated through inclusion in Article 29 of the TRIPS Agreement, the requirement that the country of origin of source material be identified in patent applications.⁸ India has also suggested that a provision be incorporated into the TRIPS Agreement, which provides that patents inconsistent with Article 15, the access provision of the CBD, must not be granted.⁹

Following the failure of the Seattle Ministerial Conference, as will be seen below, this agitation for the inclusion of traditional knowledge within the international intellectual property regime, shifted to WIPO, until it was picked up again at the Doha Ministerial Conference.

6 Communication from Bolivia, Columbia, Ecuador, Nicaragua and Peru, “Proposal on Protection of the Intellectual Property Rights Relating to the Traditional Knowledge of Local and Indigenous Communities”, World.
7 WT/GC/W/282.
8 WT/GC/W/147.
9 WT/GC/W/225.

Traditional Knowledge within the World Intellectual Property Organisation (WIPO)

The first major discussion of the protection of traditional knowledge at WIPO occurred in the context of the joint UNESCO/WIPO World Forum on the Protection of Folklore, which was convened in Phuket in April 1997. The Forum was principally concerned with the adequacy of copyright law to protect folkloric works, such as paintings, sculptures, drama, music and magic. At the Forum, the term "folklore" was criticised for its limited scope. For example, Mrs Mould-Idrissu, in a paper on "The African Experience on the Preservation and Conservation of Expressions of Folklore",¹⁰ observed that the western conception of folklore tended to focus on artistic, literary and performing works, whereas in Africa it was much more broad; encompassing all aspects of cultural heritage.¹¹ For example, she noted that under the Ghanaian Copyright Law of 1985, folklore included scientific knowledge.¹²

Following the Phuket meeting and responding to the concerns expressed at the Phuket Forum, WIPO, in its 1998-99 biennium, instituted a schedule of regional fact-finding missions "to identify and explore the intellectual property needs, rights and expectations of the holders of traditional knowledge and innovations, in order to promote the contribution of the intellectual property system to their social, cultural and economic development". Among the matters considered by the Expert Missions were:

- The feasibility of establishing databases of traditional knowledge;
- The need for, and possible nature and scope of, new or adapted forms of protection for expressions of folklore; and
- The use of the existing intellectual property system for the beneficial commercialisation of expressions of folklore, such as by way of multimedia and Internet technologies.

During 1998 and 1999, fact-finding missions visited Australia, Peru, South Africa, Thailand and Trinidad and Tobago. In August 1998, WIPO hosted a Roundtable on Intellectual Property and Indigenous Peoples. In the paper presented by Antonio Jacanimijoy, a representative of the Coordinating Body of Indigenous Peoples' Organisations of the Amazon Basin (COICA), a plea was made for the legal recognition of traditional knowledge.¹³ He suggested that until this was established the traditional knowledge of indigenous peoples "should be given recognition as innovations of informal and collective character".¹⁴ In November 1999, WIPO convened a World Forum on Traditional Knowledge, which addressed, for the first time, the concept of traditional knowledge as an intellectual property right.

10 WIPO doc, UNESCO-WIPO/FOLK/PKT/97/1 (17 March 1997).

11 Ibid at 3.

12 Ibid.

13 A Jacanimijoy, "Initiatives for the Protection of Rights of Holders of Traditional Knowledge, Indigenous Peoples and Local Communities", WIPO Doc, WIPO/INDIP/RT/98/4E, 15 July 1998.

14 Ibid at 8.

WIPO, Traditional Knowledge and Access to Genetic Resources

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.

In response to the invitation issued by the SCP, WIPO organised a Meeting on Intellectual Property and Genetic Resources on 17 and 18 April 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 organisations, through the conduct of appropriate legal and technical studies, and through the setting up of an appropriate forum within WIPO for future work.

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 harmonisation of patent registration procedures, an article which provided that:

1. 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 or made legally.
2. 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.

The Diplomatic Conference, which commenced on 11 May 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 1 June 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.

In a Note dated 14 September 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 in the WIPO General Assembly on "Matters Concerning Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore".¹⁵ 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 recognised practical methods of securing adequate protection for the intellectual property rights in traditional knowledge".¹⁶

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 to which 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.

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.

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 recognising rights in traditional works and knowledge currently in the public domain, and investigating

15 WIPO Doc, WO/GA/26/9.

16 *Ibid*, Annex I, 10.

machinery to limit and control certain kinds of unauthorised 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.

Finally, it was suggested that in concert with the secretariat of UPOV (The International Union for the Protection of New Varieties of Plants), the Committee could embark on the exploration of possible options for defining *sui generis* systems for the protection of genetic resources and biodiversity.

At the WIPO General Assembly, the Member States agreed on 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.¹⁷

At the first session of the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (“IGC”) held in Geneva from 30 April to 3 May 2001, the Member States determined the agenda of items on which work should proceed and prioritised certain tasks for the Committee. Principal among these was “the development of ‘guide contractual practices,’ guidelines, and model intellectual property clauses for contractual agreements on access to genetic resources and benefit-sharing”.¹⁸

At its second session, held in Geneva from 10 to 14 December 2001, the IGC formulated “Operational Principles for Intellectual Property Clauses of Contractual Agreements Concerning Access to Genetic Resources and Benefit-Sharing”, which suggested sample clauses for bioprospecting contracts.¹⁹

The third session, held in Geneva on 13 to 21 June 2002, discussed the development of a database concerning contractual practices and clauses relating to intellectual property, access to genetic resources and benefit-sharing. With regard to traditional knowledge, delegates debated a system of defensive protection (creating databases on prior art and working within existing intellectual property systems) and the

17 See “Matters Concerning Intellectual Property Genetic Resources Traditional Knowledge and Folklore”, WIPO Doc. WO/GA/26/6, 25 August 2000.

18 See WIPO Doc. WIPO/GTRKF/IC/2/3, 10 September 2001, para 1.

19 Ibid.

possibility of creating a system of *sui generis* protection, which would give rights to traditional knowledge rights-holders, including collective rights-holders.

At this session of the IGC, countries discussed two main issues regarding genetic resources: the formulation of intellectual property clauses in contracts that govern access to genetic resources, and their listing in a database; and the development by WIPO of a technical study on the possibilities to disclose specific information within patent applications. Two documents were presented by the WIPO secretariat:

- Call For Comments on Structure of Proposed Database of Contractual Practices and Clauses Relating to Intellectual Property, Access to Genetic Resources and Benefit-Sharing (WIPO/GRTKF/IC/3/3).
- Structure of Proposed Database of Contractual Practices and Clauses Relating to Intellectual Property, Access to Genetic Resources and Benefit-Sharing (WIPO/GRTKF/IC/3/4).

Creation of a database of contractual practices

The third session of the IGC discussed the conduct of a systematic survey of contractual agreements and the creation of an Electronic Database of Contractual Practices and Clauses relating to Intellectual Property, Access to Genetic Resources and Benefit-sharing. In defining the content of the questionnaire, some countries were opposed to the inclusion of human genetic resources and “derivatives” of genetic resources in the category “scope of the contract”. Moral and religious reasons were invoked, as well as differences in legislation regulating these various matters. It was finally decided to exclude human genetic resources and derivatives from the Database and the Questionnaire.

Also discussed was the request by the COP for the WIPO Secretariat to prepare a technical study on methods, consistent with obligations in treaties administered by the WIPO, for requiring the disclosure within patent applications of, *inter alia*:

- genetic resources utilised in the development of the claimed inventions;
- the country of origin of genetic resources in the claimed inventions;
- associated traditional knowledge, innovations and practices utilised in the development of the claimed inventions;
- the source of associated traditional knowledge, innovations and practices;
- evidence of prior informed consent.

Delegates debated the expected outcomes and impacts of the Technical Study, raising two concerns. First, some countries noted that other WIPO committees and other international forums including the TRIPS Council are discussing the issue of disclosure, and asked how the work in these bodies would relate. Some countries were concerned about how the Technical Study may impact discussions in other fora such as the TRIPS Council and the CBD.

Second, countries also debated the question of whether disclosure requirements of the type to be considered in the Technical Study, are consistent with other international obligations. The United States, for example, argued that identification of the origin of genetic resources, although an important issue that can be studied by WIPO, cannot be a substantive legal requirement for patentability under Article 27 of the TRIPS Agreement.

Traditional knowledge

Inventory and databases of traditional knowledge

The Committee discussed the need to expand an existing non-exhaustive WIPO list of traditional knowledge-related periodicals, many of which examine traditional knowledge at a practical and technical level. The goal of this expanded compilation would be to publish disclosed traditional knowledge in order to assist patent examiners to search for prior art, and thereby reduce the likelihood of misappropriation.

The Committee noted the need to link this work with the related work of the Task Force on Classification of Traditional Knowledge, part of the Committee of Experts of the Special Union for the International Patent Classification. Specifically, the Committee proposed five activities: 1) ensuring that a basic amount of traditional knowledge constitutes part of Patent Cooperation Treaty minimum documentation; 2) uploading this traditional knowledge information onto the WIPO website; 3) sharing traditional knowledge resources with patent authorities and examiners; 4) conducting an examination of the continued work of the Task Force on Classification of Traditional Knowledge; and 5) preparing an intellectual property documentation toolkit.

Representatives of indigenous peoples asked whether the existing WIPO compilation was compiled with prior informed consent. WIPO acknowledged that for many of the inventory entries, it is difficult to ascertain whether the original traditional knowledge-holders have given prior informed consent. Some delegations expressed concern over the kind of knowledge that should be included in databases and whether it should extend to cover oral knowledge, disclosed knowledge, and/or undisclosed knowledge. Some delegations expressed concern that existing national systems of IP protection are not well-suited to protect traditional knowledge because they do not meet the criteria of novelty and originality as established by internationally adopted standards. Still other delegations disagreed as to whether traditional knowledge is in the public domain or not. Some national systems of protection, such as geographical indications, it was agreed, were collectively considered effective. Some countries were opposed to this later approach.

Elements of a sui generis system for the protection of traditional knowledge

The main subject of discussion at the third session was the elements of a *sui generis* System for the Protection of Traditional Knowledge. Delegations debated the structure and subject matter of protection, whether any future system, if established, would be a harmonised system of national IP protection, or a *sui generis* system. The Chair stressed that the discussions were not to be about whether a system should be set up, but rather, in the event such a system were to be established, what technical components would be included in such a system.

Definition terms relating to traditional knowledge

Delegations could not come to a final consensus on operational definitions relating to traditional knowledge (the subject of document WIPO/GTRKF/IC/3/9). While the United States wanted a clear definition of traditional knowledge before agreeing to a definitive system of protection, others felt that a consensual definition was not possible, given the diversity and variation of traditional knowledge subject matter, defined and reflected by the local and cultural realities of traditional communities. Some delegations noted in response that the lack of definition of the subject matter of patents had not prevented protection in that area, and thus traditional knowledge should be protected despite the lack of a universal definition. Some added that a definition of traditional knowledge could be decided nationally, while still having a global system of protection.

The Fourth Session of the IGC met at Geneva from 9 to 17 December 2002. It was largely taken up with a review of the work which had been undertaken on the various initiatives which had been launched at the previous session. A draft outline of a basis for the development of an intellectual property toolkit for traditional communities was presented (WIPO/GTRKF/IC/4/5), as was a report on an electronic questionnaire on contractual practices and clauses relating to intellectual property (WIPO/GTRKF/IC/4/10).

The bulk of the session was taken up with presentations on national and regional experiences with specific legislation for the legal protection of traditional cultural expressions.

Traditional Knowledge as Searchable Prior Art

“Prior art” generally refers to the entire body of knowledge which is available to the public before the filing date or, if priority is claimed, before the priority date, of an application for patents, utility models and industrial designs. The identification of prior art constitutes a cornerstone for the substantive examination of applications for these titles, since requirements such as novelty and inventive step are established by comparing the claimed subject matter with the relevant prior art.

In criticising alleged instances of biopiracy, in relation to the obtaining of intellectual property rights pertaining to traditionally utilised plants such as Indian Neem, Turmeric and Basmati Rice, it has been claimed that patents have been granted for traditional knowledge-related inventions which did not satisfy the requirements of novelty and inventive step when compared with the relevant prior art.²⁰ This prior art consisted of traditional knowledge, which had not apparently been identified by the patent-granting authority during the examination of the patent application.

The practical difficulty which patent examiners have, in identifying relevant traditional knowledge as prior art, arises from the fact that they do not have access to traditional knowledge information in classified non-patent literature and because there are no effective search tools for the retrieval of such information.

The WIPO Intergovernmental Committee has begun to address practical measures to establish linkages between IP Offices and traditional knowledge documentation initiatives. The objectives of this initiative include:

- enabling traditional knowledge documentation initiatives to make public domain traditional knowledge data available to IP Offices,
- allowing IP Offices to integrate public domain traditional knowledge documentation into their existing procedures for the filing, examination, granting and publication of IP titles, and
- facilitating the electronic exchange and dissemination of standardised documentation data within existing IP information systems and for the general public, as appropriate.²¹

The practical purposes of this project would be to (i) avoid the grant by IP Offices of patents for traditional knowledge-based inventions which are not novel and non-obvious; (ii) avoid the costs for traditional knowledge holders and other interested third parties of challenging such patents; and (iii) facilitate recognition of the technological value of traditional knowledge by all users of non-patent literature, including IP Offices, industry, researchers and the general public.²²

Constraints upon the recognition of traditional knowledge as prior art

A number of the characteristics of traditional knowledge present difficulties in identifying the prior art effect of technological information. These include:

20 "Intellectual Property Aspects of Traditional Agricultural Knowledge", in *IP in Biodiversity and Agriculture: Regulating the Biosphere*, M Blakeney and P Drahos (eds) (Sweet & Maxwell London 2001) at 29-52.

21 WIPO Doc, WIPO/GRTKF/IC/2/6, 1 July 2001, para 6.

22 *Ibid*, para 7.

- (a) The transmission of traditional knowledge through oral communication. This requires the codification and fixation of traditional knowledge into what it is not.
- (b) Traditional knowledge systems tend to dynamic evolution without necessarily being identified as “new”.
- (c) Traditional knowledge is expressed in local languages and its expression is contingent upon such languages.
- (d) The transfer of knowledge from oral into written, printed, and electronic forms may involve a cultural, semantic and symbolic transformation of the knowledge, which may affect the value of databases as a tool for the conservation of culture and knowledge.
- (e) As knowledge must be in the public domain to be considered as prior art, this may provide some difficulties in those communities where knowledge is to be kept confidential.

Given the evolutionary nature of traditional knowledge, in most cases the date of disclosure cannot be clearly determined, which may provide a difficulty in adjudicating the question of priority.

Definitions of prior art and their relationship to traditional knowledge

(a) *Patent Cooperation Treaty (PCT)*

Under the PCT, Article 15(2) provides that:

relevant prior art shall consist of everything which has been made available to the public anywhere in the world by means of written disclosure (including drawings and other illustrations) and which is capable of being of assistance in determining that the claimed invention is or is not new and that it does or does not involve an inventive step (ie, that it is or is not obvious), provided that the making available to the public occurred prior to the international filing date.

Rule 33.2 of the Regulations Under the PCT on “Fields to be Covered by the International Search” provides that the international search “shall cover all those technical fields, and shall be carried out on the basis of all those search files, which may contain material pertinent to the invention”. The Regulations Under the PCT provide that “[i]n so far as possible and reasonable, the international search shall cover the entire subject matter to which the claims are directed or to which they might reasonably be expected to be directed after they have been amended”.

Rule 33.1(b) of the Regulations Under the PCT provides that oral disclosure, use, exhibition or other means of disclosure are not relevant prior art for the purposes of an international search unless substantiated by a written disclosure.

Article 15(4) of the PCT provides that in the international search, the competent International Searching Authority, which undertakes the search, “shall endeavour to

discover as much of the relevant prior art as its facilities permit, and shall, in any case, consult the documentation specified in the Regulations”.

Article 27(5) of the PCT expressly preserves the freedom of Contracting Parties to apply the respective definitions of prior art in their national laws when determining the patentability of an invention claimed in an international application.

(b) *Draft substantive Patent Law Treaty*

The draft Substantive Patent Law Treaty, which was submitted to the fifth session of the WIPO’s Standing Committee on the Law of Patents (SCP), held in Geneva from 14 to 19 May 2001, contained two alternatives for a draft article on the definition of prior art. The draft provisions on the definition of prior art provide that any information made available to the public, anywhere in the world, in any form, including in written form, by oral communication, by display and through use, shall constitute prior art, if it has been made available to the public before the filing date, or, where applicable, the priority date. At its fifth session, an NGO representative noted that “the capturing of information, including information ... in the field of traditional knowledge, was important”.²³

(c) *European Patent Convention*

Article 54(2) of the European Patent Convention (EPC) provides that:

The state of the art shall be held to comprise everything made available to the public by means of a written or oral description, by use, or in any other way, before the filing of the European patent application.

The *Guidelines for Examination in the European Patent Office* (EPO) emphasise that “[t]he width of this definition should be noted. There are no restrictions whatever as to the geographical location where, or the language or manner in which the relevant information was made available to the public; also no age limit is stipulated for the documents or other sources of the information”. Thus all traditional knowledge comprised in this wide definition of the state of the art is recognised as prior art by the EPO.

(d) *Japan*

A specific reference to traditional knowledge as prior art is made in the Japanese Patent Office’s (JPO) “Operational Guidelines on Treatment of Technical Information Disclosed on the Internet as Prior Art” issued on 10 December 1999 to

23 See WIPO doc, SCP/5/6 Prov, para 78.

offer guidance on the treatment as prior art of “inventions which became available to the general public through telecommunication lines prior to the filing of patent applications”.

Information of an online traditional knowledge database is considered, under the Guidelines, as being available to the general public if it is linked with any other site on the Internet, registered with any search engine, or if the URL of the site is published in a means providing information to the general public. The online traditional knowledge database would be considered as accessible by unspecified persons even if access requires a password, if anybody can access it by acquiring a password through a set of non-discriminating procedures. An online database that is accessible by the mere payment of a fee is considered as a website accessible by unspecified persons.

The Guidelines also provide that, in principle, information without an indication of the time of publication is not to be cited by the examiners. The date of publication of traditional knowledge on the Internet is the date it is uploaded. An earlier date must be proven through the presentation of alternative evidence.

(e) *United States of America*

In the USA, prior foreign activity anticipates a US patent only if the foreign activity is described in a printed form, including a patent or patent application. However, prior foreign knowledge, use and invention are excluded from the prior art relevant to a U.S. patent application.

In the challenge to the US patent granted in relation to Turmeric, it was revealed that the USPTO examiners were not able to ascertain the existence of traditional knowledge revealed in non-patent literature which taught the use of the invention. To deal with this issue of the need for creating more easily accessible non-patent literature databases that deal with traditional knowledge, the USPTO has suggested that “... with the help of the developing countries, traditional knowledge can be documented, captured electronically, and placed in the appropriate classification systems so that it can be more easily searched and retrieved”.²⁴ This would provide a framework to integrate traditional knowledge databases into patent information systems which are seamlessly searchable for patent examination purposes.

24 Letter by Mr Robert W Saifer, Director, International Liaison Staff, United States Patent and Trademark Office (USPTO), addressed to Dr RA Mashelkar, Director General, Council of Scientific and Industrial Research (CSIR), Government of India, dated 27 August 1999, quoted in WIPO Doc. WIPO/GRTKE/IC/2/6, 1 July 2001, para 65.

Proposals to Improve Access to Traditional Knowledge-related Non-patent Literature

The WIPO Intergovernmental Committee has recommended the development of contacts between IP Offices and the various traditional knowledge documentation initiatives to enable those offices to integrate standardised traditional knowledge documentation into their procedures for filing, examination, publication and granting of intellectual property titles.²⁵ Among the possible measures that could be taken by IP Offices for an improved integration of traditional knowledge into prior art searches, WIPO suggests measures for: (1) the classification of traditional knowledge documentation in patent documents and non-patent literature, in particular through the International Patent Classification; (2) the integration of traditional knowledge-related periodicals in minimum documentation lists for non-patent literature; (3) the further evolution of search and examination procedures; and (4) increased searching of databases and digital libraries containing traditional knowledge documentation data.

WIPO has proposed the establishment of an international database of traditional knowledge which would provide a network of regional, national and local databases and would function similar to the Clearing House Mechanism of the CBD.²⁶ The knowledge recorded in this database should be organised in standardised classifications.

Obviously, for the IP system to accommodate traditional knowledge the traditional knowledge documentation initiatives of indigenous and local communities must be prepared to provide documentation data to national and regional patent offices. The initiatives must, however, be with the approval and involvement of the indigenous and local communities which are the holders of such knowledge, innovations and practices.

The harmonisation of existing IP documentation standards and traditional knowledge documentation standards, and their consistent application, would be important for IP Offices to enable them to integrate standardised traditional knowledge documentation data into their existing procedures for filing, examining, publishing and granting IP titles.

An important matter to consider, particularly in the field of pharmaceutical patenting, is the extent to which documentation initiatives might prejudice the commercial exploitation of patenting by the custodians of the traditional knowledge. Guidance has to be provided to traditional communities on this issue.

25 Ibid, para 66.

26 Ibid, para 94.

Biodiversity, Conservation and Traditional Agricultural Knowledge

As an exploration of the practical implications of the protection of traditional knowledge, the contribution which has been made by the knowledge of indigenous peoples and traditional farmers in the development of new crop types and biodiversity conservation will be examined, on a case study basis. 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 utilise improved varieties are obliged to pay for them. The economic value of biological diversity conserved by traditional farmers for agriculture is difficult to quantify.²⁷ 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”²⁸ 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.

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. 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.²⁹

This part of the paper examines a number of recent cases in which traditional agricultural knowledge has been converted into intellectual property rights and explores the possibilities for the protection of this knowledge within the context of the CBD and TRIPS.

The Consultative Group on International Agricultural Research (CGIAR)

The principal *ex situ* collection of germplasm available for agricultural research is maintained by the CGIAR. This organisation, founded in 1971, is an informal

27 See, for example, S Brush, *Providing Farmers’ Rights Through In Situ Conservation of Crop Genetic Resources* (University of California Berkeley 1994).

28 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.

29 McNeely, ‘Biodiversity and Agricultural Development: The Crucial Institutional Issues’ in DR Lee and CB Barrett, (eds), *Tradeoffs or Synergies? Agricultural Intensification, Economic Development and the Environment* (CABI Wallingford 2001) 399 at 404.

association of public and private donors that supports an international network of 16 international agricultural research centres (IARCs), each with its own governing body. The major sponsors are the UN Food and Agriculture Organisation (FAO), the World Bank, the Rockefeller and Ford Foundations, the United Nations Development Programme (UNDP), the United Nations Environment Programme (UNEP) and the aid programmes of the European Union and a number of individual countries. With a budget of some US\$340 million per annum, the CGIAR oversees the largest agricultural research effort in the developing world.

This agricultural research commenced with the work of Norman Borlaug, an American plant breeder, who won the Nobel Prize in 1970 for his work in developing high-yielding wheat varieties for Mexico. Borlaug, was the founding father of the Centro Internacional de Mejoramiento de Maiz y Trigo (CIMMYT), which became the first of the CGIAR centres. Following the establishment of CIMMYT, 15 other international agricultural research centres have been established, each focussing on crops and materials of interest to developing countries.³⁰ In addition to conducting research, the GGIAR, supports a collection of germplasm, which currently comprises over 600,000 accessions of more than 3,000 crop, forage and pasture species which are held at the research centres. These germplasm collections are held under the auspices of the FAO "in trust for the benefit of the international community, in particular the developing countries", include up to 40% of all unique samples of major food crops held by gene banks worldwide. The FAO Commission on Genetic Resources for Food and Agriculture determines the policy under which the network of *ex-situ* collections operates.

In addition to the so-called "designated germplasm", which is held under the trust relationship with the FAO, the various CGIAR centres have developed "elite germplasm" and biological tools, such as isogenic lines, mutants and mapping populations, from the materials which have been deposited with them.

Since the late nineties, difficult questions have been raised concerning the legal status of the germplasm collections of the agricultural research institutes which are members of the CGIAR. At the time of their establishment, 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.³¹

30 These centres are: the Centro Internacional de Agricultura Tropical (CIAT), Center for International Forestry Research (CIFOR), Centro Internacional de la Papa (CIP), International Center for Agricultural Research in the Dry Areas (ICARDA); International Center for Living Aquatic Resources Management (ICLARM), International Center for Research in Agroforestry (ICRAF), International Crop Research Institute for the Semi-Arid Tropics (ICRISAT); International Livestock Research Institute (ILRI), International Institute of Tropical Agriculture (IITA), International Plant Genetic Resources Institute (IPGRI) International Rice Research Institute (IRRI) and the West Africa Rice Development Association (WARDA).

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

Biopiracy episodes

The status of the CGIAR collections was questioned in a series of so-called biopiracy episodes in which intellectual property rights were sought in relation to germplasm obtained from a number of CGIAR centres

(a) 1998 Australian 'Biopiracy' Episode

Germplasm ownership concerns were raised in 1998 as a consequence of Plant Breeder's Rights applications made in Australia by a number of agricultural research institutes in relation to a pea vine 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, Syria.³² 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 material.³³

The 14 February 1998 issue of *New Scientist* contained an editorial and leading article on the alleged biopiracy of two Australian agricultural agencies. The two agencies: Agriculture Western Australia and the Grains Research and Development Corporation (GRDC) had apparently applied for Plant Breeder's Rights (PBR) under the Australian Plant Breeder's Rights Act, 1994, in relation to two species of chickpea which had been bred from material which had been provided by the International Crop Research Institute for the Semi-Arid Tropics (ICRISAT). These PBR applications had to meet the statutory tests prescribed in section 43 of the Act that the new variety has a breeder, that it is distinct, uniform and stable and that it has not been or has only recently been exploited. The Australian Plant Breeder's Rights Office did not have an opportunity to make a determination on these matters because the furore caused by these applications led to their withdrawal, prior to determination.

32 "Editorial. Let We Starve", No 2121, *New Scientist*, 14 February 1998, 3; Edwards and Anderson, 'Seeds of Wrath', *ibid* at 14.

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

The *New Scientist* editorialised that “it was hard to imagine what two Australian government agricultural agencies thought that they were up to when they applied for property rights on chickpeas grown by subsistence farmers in India and Iran”.³⁴ A feature article in the *New Scientist* carried an accusation from a spokesperson from the South Asian Network on Food, Ecology and Culture which described the PBR applications as “blatant biopiracy” by “privatising seeds that belong to our farmers and selling them back to us”.³⁵

Research by the Rural Advancement Foundation International (RAFI) suggested that there were numerous other instances of “biopiracy” by other Australian agricultural research institutes. Reacting to the biopiracy controversy, CGIAR called for a moratorium on the granting of intellectual property rights over plant germplasm held in its centres. CGIAR Chairman, Dr Ismail Serageldin, explained the call for a moratorium as “the strongest signal the CGIAR can send governments to ensure that these issues be resolved and the materials in the CGIAR remain in the public domain”.³⁶ In Australia, serious concerns were expressed about the implications which such a moratorium would have, particularly for its cultivation of cereals. Consequently, to prevent a recurrence of this incident, the operating regulations of the Australian Plant Breeders Rights Office were amended to oblige applicants for PBRs in relation to varieties derived from germplasm obtained from CGIAR Centres, to document that such applications were made with the permission of the relevant Centre.

Responding to concerns about the impact of intellectual property rights upon the operation of the CGIAR, it commissioned a report on the use of proprietary technologies by CGIAR Centres by the International Service for National Agriculture Research (ISNAR), which operates as its legal advisory body.³⁷ The report noted the burgeoning use of proprietary technologies by the centres and recommended that they undertake audits of their intellectual property management policies. ISNAR established a Central Advisory Service to provide legal counsel for the centres on intellectual property matters.

An issue which has not yet been addressed by the CGIAR or 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.

34 “Editorial. Lest We Starve”, No 2121, *New Scientist*, 14 February 1998, at 3.

35 Edwards and Anderson, “Seeds of Wrath”, *ibid* at 14.

36 CGIAR Press Release “CGIAR Urges Halt to Granting of Intellectual Property Rights for Designated Plant Germplasm”, 11 February 1998. <http://www.cgiar.org/80/germrel.htm>.

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

(b) *Blight-resistant Rice*

In the late 1970s a strain of rice from Mali, *Oryza longistaminata*, was identified by a researcher, working in Cuttack, North India, as being resistant to bacterial blight, a disease which particularly afflicts rice. In 1978 this resistant sample was taken to the International Rice Research Institute (IRRI) in Los Banos, Philippines for further investigation. Over a fifteen-year period, IRRI researchers developed through conventional breeding, a high-yielding, blight resistant strain of rice. The IRRI researchers identified that this resistance was contributed by a single locus called Xa21. A post-doctoral research fellow, Dr Ronald, from the University of California at Davis (UC Davis), who was working at IRRI, was permitted with co-workers at Stanford University to map, sequence and clone the Xa21 gene. The molecular mapping process was facilitated by the construction of a BAC library utilising a biological tool provided by IRRI.

On 7 June 1995, the Regents of the University of California filed a patent application for "Nucleic acids, from *Oryza sativa*, which encode leucine-rich repeat polypeptides and enhance *Xanthomonas* resistance in plants". The inventors named in the application were Dr Ronald and her co-workers. The patent was granted by the United States Patents and Trademark Office on 12 January 1999 (US Patent 5,859,339).

This patent generated some controversy in CGIAR circles because it was perceived to compromise IRRI's research efforts and those of its clients in the rice-producing regions of Asia. Bacterial blight is not a particular problem for US rice producers and a primary effect of the patent was to prevent the export of bacterial blight resistant rice, utilising the patent, to the USA. This patent also raised the question of equitable compensation, at least for the traditional farmers of Mali who had conserved *O. longistaminata*. The UC Davis dealt with the issue of compensation by establishing a Genetic Resources Recognition Fund (GRRF) as a mechanism to share benefits arising from the commercial utilisation of its patent. It was also acknowledged that in the absence of this sort of mechanism, it would have been "more difficult for the university in the future to obtain research access to developing countries' national genetic materials".³⁸

UC Davis also agreed to allow non-commercial researchers access to the gene, provided they did not develop commercial products based on that gene. The University also agreed that "IRRI would have full rights to develop new rice varieties incorporating cloned Xa21 and distribute this material as well as the clone to developing countries".³⁹

The attempts by UC Davis to provide a mechanism for the sharing of benefits with traditional peoples to be derived from its patent on Xa21 were analysed in a case

38 P Ronald, quoted in WIPO/UNEP, *The Role of Intellectual Property Rights in the Sharing of Benefits Arising from the Use of Biological Resources and Associated Traditional Knowledge Selected Case Studies* (WIPO Geneva 2001) at 13.

39 Ibid at 14.

study by the World Intellectual Property Organisation and the United Nations Environment Programme.⁴⁰ This study found that with one exception, the traditional peoples of Mali regarded *O. longistaminata* as a weed with a very low grain yield. It concluded that in designing benefit-sharing arrangements:

- The stakeholders are not limited to the formal scientific research institutions of the country of origin of the genetic resource;
- The ethnobotanical knowledge of local PGRFA is not necessarily and only held by local landowning farmers, but can also be held by local communities that are landless and subsist on mixed modes of income;
- The ethnobiological knowledge is not limited to indigenous communities.⁴¹

This case study illustrates a number of the practical problems with proposals for benefit-sharing under the CBD. First, the research into the blight resistant properties of *O. longistaminata* commenced prior to the CBD coming into force; secondly, the local farming and indigenous communities were largely unaware of these properties; and thirdly, the itinerant poor community, which made use of the rice would be unlikely to enjoy any of the benefits which UC Davis could make available. It is for this reason that benefit-sharing norms are being developed by the international community.

(c) *Enola Bean*

On 13 April 1999 the US Patent and Trademarks Office granted Patent nNo 5,894,079 to Larry Proctor for an invention described in the patent grant as relating to “a new field bean variety that produces distinctly colored yellow seed which remain relatively unchanged by season”. On 28 May 1999, Larry Proctor also obtained a US Plant Variety Protection Certificate on the bean variety.

Larry Proctor was the president of a Colorado (USA) based seed company, PODNERS. Upon the grant of the patent, this company was reported to have written to all the importers of Mexican beans in the United States, requiring the payment of a royalty of six cents per pound.⁴² According to Miguel Tachna Felix, of the Agricultural Association of Rio Fuerte, this would have meant an immediate drop in export sales, over 90%. POD-NERS was reported to have brought infringement actions against two companies that were selling Mexican yellow beans in the US. In January 2000, the Mexican government announced that it would challenge the US patent. Jose Antonio Mendoza Zazueta, Under-Secretary of Mexican Rural Development declared that “We will do everything necessary, anything it takes, because the defence of our beans is a matter of national interest.”⁴³ RAFI denounced the yellow bean patent as ‘Mexican

40 See n 17.

41 Ibid at 24.

42 ‘Mexican Bean Biopiracy’, Biotechnology Notice Board, posted by: PANUPS panupdates@panna.org, 24 January 2000.

43 Quoted, *ibid*.

bean biopiracy' and demanded that the patent be legally challenged and revoked. RAFI formally requested that FAO and the CGIAR investigate the patent as a likely violation of their 1994 Trust agreement.⁴⁴

On 20 December 2000, the Centro Internacional de Agricultura Tropical (CIAT) filed a formal request for re-examination of the US patent concerning the yellow bean, which was alleged to be the Mexican Enola bean.⁴⁵ CIAT's official request for re-examination of the patent stated that the claims for inventiveness contained in the patent failed to meet the statutory requirements of novelty and non-obviousness, and ignored the prior art widely available in the literature.⁴⁶ The challenge was particularly critical of the patent's claim of exclusive monopoly on any *Phaseolus vulgaris* (dry bean) having a seed color of a particular shade of yellow, pointing out that 'it will make a mockery of the patent system to allow statutory protection of a color per se.' Although there was no evidence that the patent owner obtained his yellow beans from CIAT's gene bank, the patent challenge noted that CIAT maintained some 260 bean samples with yellow seeds, and 6 of the accessions were "substantially identical" to claims made in the patent.⁴⁷

CIAT's patent challenge also asserted that the yellow bean was 'misappropriated' from Mexico, and that this was in breach of Mexico's sovereign rights over its genetic resources, as recognised by the CBD. The USPTO is currently determining this challenge.

(d) *Yacon*

In November 1999, five traditional Peruvian varieties of yacon held in the genebank at the International Potato Center (CIP) in Peru, were distributed to the Peruvian Ministry of Agriculture, which passed them to researchers in Japan. Yacon (*Smallantus sonchifolius*) an ancient Andean crop, is eaten raw as a fruit in the Andes. It has a high fructose content with a high percentage of insulin and leaves reported to have antidiabetic properties.⁴⁸ CIP's Potato Germplasm Curator, Dr Zozimo Huaman, alleged that this distribution of yacon by CIP was in breach of its trust obligations, particularly because the biosafety requirements of the Centre were apparently not followed.⁴⁹ Japanese researchers, in a seminar at CIP in September 2000, indicated that the area cultivated with yacon in Japan had been greatly increased in recent years and that it was utilised as a vegetable, pickles and juices. They also reported that the National Shikoku Agriculture Experiment Station had released the first commercial variety named "Sarada-Otome" on 25 August 2000. Dr Huaman expressed concern

44 "Mexican Bean Biopiracy", RAFI Geno-Types, 15 January 2000.

45 RAFI, "Enola Bean Patent Challenged", News Release, 5 January 2001, www.rafi.org.

46 Ibid.

47 Ibid.

48 National Research Council, *Lost Crops of the Incas: Little Known Plants of the Andes with Promise for World-wide Cultivation* (National Academy Press Washington DC 1989).

49 See, for example, Z Huaman, 'Unethical distribution to Japan of Yacon held in trust by CIP' Circulated on the biodiv-conv listserv run by BIONET (<http://www.bionet-us.org>), 7 April 2001.

that, apparently because of plant breeders' rights, the Japanese researchers were not prepared to send germplasm of "Sarada-Otome" to be tested in Peruvian farmers' fields. He questioned the equity of denying to a source country, new derivatives of deposited germplasm.⁵⁰

Upon learning of Dr Huaman's allegation, CIP requested its Genetic Resources Policy Committee (GRPC) to determine if any violation of the FAO agreement had occurred. The GRPC, chaired by Dr MS Swaminathan, was established by CIP as an independent advisory committee made up of internationally-known scientists as well as representatives of the NGO community, private sector, and developing and developed country governments. The committee concluded that CIP had no right to interfere in Peru's sovereign decision to send the germplasm to Japan and commended CIP for its proper management of its germplasm held "in-trust".⁵¹

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 mission."⁵² This proprietisation of public sector agriculture research is questioned, particularly by those NGO's opposed to patenting in the life sciences.⁵³

(e) *Nuna Beans*

On 21 March 2000 a patent was granted to a US corporation⁵⁴ in relation to a "beannut popping bean" apparently derived from crosses involving at least 33 Andean nuna bean varieties from Peru, Bolivia, Ecuador, and Colombia. RAFI reported that a meeting of a tribunal of indigenous elders from six Andean communities that grow nuna beans met in February 2001 and condemned the patenting as biopiracy of their Andean heritage and demanded that CIAT - The International Center for Tropical Agriculture, the CGIAR Centre based in Cali, Colombia - uphold its obligation under

50 Ibid.

51 Zandstra, 'Potato Center Upholds Letter and Spirit of FAO Agreement' (<http://www.bionet-us.org>), 9 April 2001.

52 CIMMYT, *Policy on Intellectual Property*, Article III.4.v, <www.cimmyt.org/resources/btaining/seed/ip_policy/html/ip-policy.htm>.

53 See, for example, 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.

54 US Patent No 6,040,503; Patent Cooperation Treaty Patent No WO99/11115.

a United Nations “trust agreement” to keep farmer-bred bean varieties in the public domain.⁵⁵

RAFI reported the views of a number of scientists working with nuna who were concerned that the patent would limit improvements in the crop to the prejudice of the traditional Andean peoples. In particular it was observed that toasting nunas used less fuel than boiling beans, a feature important to economic and environmental conditions in areas of the world where fuel is scarce. Additionally, RAFI reported that the US patent also prejudiced a stratagem to use popping beans grown in the Andes as a substitute for illicit crops.

The patent was described as “particularly offensive to Andean farmers and indigenous people” because it extended to crosses involving at least 33 Andean nuna varieties traditionally bred and developed over centuries in Peru, Bolivia, Ecuador, all of which were freely provided by Andean farming communities, “who allowed their bean varieties to be put into the public realm in order to ensure the continued maintenance of the world’s seed biodiversity”. Nine of these varieties were held in CIAT’s international bean collection as designated in-trust accessions, all being farmers’ varieties collected in Peru.

This case has been adopted by a number of NGOs as a test of the international intellectual property community’s resolve to support the conservation and development of indigenous knowledge.

(f) *Peruvian Maca*

Indigenous peoples’ and farmers’ organisations from the Andes and the Amazon meeting at the Ecological Forum in Lima, on 28 June denounced US patents on maca, the high-altitude Andean plant (of the *Cruciferae* [mustard] family) that has been grown for centuries by indigenous peoples in the Puna highlands of Peru, both as a staple food crop and for medicinal purposes.

The US patents were issued in relation to the Viagra-like therapeutic aspects of Maca.⁵⁶ The Ecological Forum requested that CIP, as promoter and protector of maca seed, take action to prohibit intellectual property claims in relation to all Andean crop germplasm and their genetic components, and indigenous knowledge related to these genetic materials.⁵⁷

55 RAFI

56 US Patent No 6,093,421 - Biotics Research Corporation - Issued: 25 July 2000 - Title: Maca and antler for augmenting testosterone levels; US Patent No 6,267,995 - Pure World Botanicals, Inc. - Issued: 31 July 2001 - title: Extract of *Lepidium meyenii* roots for pharmaceutical applications. Applications pending in Australia, the European Patent Office, and at World Intellectual Property Organisation (WIPO).

57 www.etcgroup.org, 3 July 2002.

CGIAR's response to the 'biopiracy' episodes

In 1992, in anticipation of the Rio Earth Summit, the CGIAR had adopted a "Working Document on Genetic Resources and Intellectual Property". This provided that:

- Material from the genebanks at the centers will continue to be freely available in accordance with the 1989 CGIAR Policy on Plant Genetic Resources;
- Centers do not seek intellectual property protection unless it is absolutely necessary to ensure access by developing countries to new technologies and products; and
- [A]ny IPR acquired by a center are exercised without compromising in any manner whatsoever the fundamental position of the CGIAR regarding the free access by developing countries to knowledge, technology, materials and plant genetic resources.⁵⁸

In order to implement these obligations under the FAO-CGIAR Agreements, the Centers which have signed Agreements with the FAO make samples of in-trust germplasm available to requestors under a standard Material Transfer Agreement (MTA). Under this contractual agreement, when the recipient accepts the shipment of germplasm they are deemed to accept the terms of the standard MTA, which include the obligation not to claim any ownership or IPRs over the material. The obligations of the recipient include the obligation to ensure that all subsequent parties to whom the material is transferred also honour the same conditions.

The International Treaty on Plant Genetic Resources for Food and Agriculture, which was approved by the FAO Conference in November 2001 calls upon the CGIAR Centers to sign agreements with the Governing Body of the Treaty with regard to their *ex situ* collections according to which, *inter alia*, "plant genetic resources for food and agriculture listed in Annex I ... shall be made available in accordance with the provisions set out in Part IV. Plant genetic resources for food and agriculture other than those listed in Annex I and collected before its entry into force that are held by IARCs shall be made available in accordance with the provisions of the MTA currently in use pursuant to agreements between the Centres and the FAO.

A Multilateral System ("MLS") was established by the International Treaty to facilitate access to plant genetic resources and for the fair and equitable sharing of benefits arising from their use.

⁵⁸ "CGIAR Working Document on Genetic Resources and Intellectual Property", (1992) CGIAR Mid-term Meeting. In: *Summary of Proceedings and Decisions*, Istanbul. World Bank, Washington, DC.

The Way Forward

Regional agreements on access and benefit-sharing

The implementation of CBD principles has been attempted in two draft regional framework agreements: (a) the draft ASEAN Framework Agreement on Access to Biological and Genetic Resources (“the draft ASEAN Framework Agreement”); and (b) Decision 391 on a Common System on Access to Genetic Resources of the Commission of the Cartagena Agreement.

These framework agreements have been developed by regional economic integration organisations in an endeavour to set minimum standards for determining access to genetic resources within a region; to ensure that national access regulations are uniform and consistent with the identified minimum standards; and to strengthen the negotiating capacity of the member countries to the framework agreement. These framework agreements mirror the negotiating strategy of the earlier framework agreements on intellectual property.⁵⁹

Article 16 of Decision 391 provides in Chapter I that “[a]ll access procedures must include the presentation, admission, publication and approval of an application, signature of a contract, issue and publication of the corresponding resolution and a declaratory record of actions linked with such access”.

Contractual agreements may be used to establish the specific terms and conditions for access and benefit-sharing in respect of individual genetic resources and associated subject matter, such as derivatives or biodiversity-related traditional knowledge. Typically, it is required that the terms of the access contract shall comply with the contents of the framework agreement and the national access legislation of the relevant member country of the framework agreement. The framework agreements may also include provisions or measures pertaining to intellectual property issues which may relate to the rights and obligations to be established in the access contracts stipulated by the framework agreement.

The standards established in framework agreements are typically implemented into national law through national access legislation for genetic resources. Additionally, model laws for access to genetic resources are being developed by regional integration organisations, such as the Organisation of African Unity. These model laws also foresee, as an implementing tool for national access legislation, the use of contractual agreements between the National Competent Authority and the concerned local community or communities on the one hand and the applicant or collector on the other.⁶⁰

59 See M Blakeney, “The Role of Intellectual Property in Regional Commercial Unions,” (1998) 4 *Journal of World Intellectual Property* 691.

60 See, for example, Articles 7(2) and 8 of the Draft African Model Legislation for the Protection of the Rights of Local Communities, Farmers and Breeders and for the Regulation of Access to Biological Resources of the Organisation of African Unity (OAU), as contained in Annex III of document OAU/AEC/TD/MIN/7(iii).

National access legislation

At the national level, more than thirty countries had reportedly promulgated, or were in the process of developing, national legislation on access to genetic resources and benefit-sharing.

The pioneering national legislation was the Philippines Executive Order No 247, “Prescribing a Regulatory Framework for the Prospecting of Biological and Genetic Resources, their By-products and Derivatives, for Scientific and Commercial Purposes, and for Other Purposes”, which became law in 1995.

The purpose of EO 247 is identified in the Preamble as regulating “the prospecting of biological and genetic resources so that these resources are protected and conserved, are developed and put to the sustainable use and benefit of the national interest”. This includes the identification and recognition of “the rights of indigenous cultural communities and other Philippine communities to their traditional knowledge and practices when this information is directly and indirectly put to commercial use”.

The Preamble also asserts that “wildlife, flora and fauna, among others, are owned by the State and the disposition, development and utilisation thereof are under its full control and supervision”. However, the State’s resource rights are not absolute, in that prospecting is only permitted within “the ancestral lands and domains of indigenous cultural communities ... with the prior informed consent of such communities; obtained in accordance with the customary laws of the concerned community”. Permission for bioprospecting depends on a research agreement between the bioprospector and the government.

For an agreement to be granted, a research proposal must be submitted to the government, with a copy submitted to any community that may be affected. At a minimum, the agreement must contain a provision whereby the bioprospector informs the government and affected communities if a commercial product results from the research, with a provision for payment of royalties to the government and community if commercial use results from any biogenetic resources taken.

This pioneering legislation has been criticised for the complexity of the implementing regulations, with very few research permits being issued.⁶¹

61 See G Dufield, *Developing and Implementing National Systems for Protecting Traditional Knowledge: A Review of Experiences in Selected Developing Countries* (UNCTAD, 2001).