WIPO/IP/UNI/DUB/04/10
ORIGINAL: English
DATE: April 2004

AJMAN UNIVERSITY OF SCIENCE AND TECHNOLOGY

ASSOCIATION OF ARAB UNIVERSITIES

THE ASSOCIATION OF ARAB PRIVATE INSTITUTIONS FOR HIGHER EDUCATION

WORLD INTELLECTUAL PROPERTY ORGANIZATION

WIPO NATIONAL SEMINAR ON INTELLECTUAL PROPERTY FOR FACULTY MEMBERS AND STUDENTS OF AJMAN UNIVERSITY

organized by
the World Intellectual Property Organization (WIPO)

in cooperation with
Ajman University of Science and Technology (AUST),
the Association of Arab Universities
and
the Association of Arab Private Institutions for Higher Education

Ajman, May 5 and 6, 2004

INTELLECTUAL PROPERTY, TRADITIONAL KNOWLEDGE AND GENETIC RESOURCES: POLICY, LAW AND CURRENT TRENDS

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Intellectual Property Rights and Agriculture

As early as the 1883 Paris Convention for the Protection of Industrial Property, agriculture was envisaged as an area of enterprise in respect of which property rights could be secured, thus Article 1(3) of the Convention had declared that

> Industrial property shall be understood in the broadest sense and shall apply not only to industry and commerce proper, but likewise to agricultural and extractive industries and to all manufactured or natural products, for example, wines, grain, tobacco leaf, fruit, cattle, minerals, mineral waters, beer, flowers and flour.

Given the state of technology in 1883, the inclusion of these agricultural subjects within the Paris Convention, was probably in the context of the protection of trade marks and indications of source. The importance of the latter was reflected in the Second Conference of Revision of the Paris Convention, held at Madrid in 1890-91, which proposed a special agreement for the repression of false indications of origin.

The first inclusion of agricultural innovations in an intellectual property statute was the US Plant Patents Act of 1930, which had been foreshadowed by the introduction in the US Congress in 1906 of a "Bill to amend the laws of patents in the interest of the originators of horticultural products". This Bill was unsuccessful, as were similar Bills introduced in 1907, 1908 and 1910. The Plant Patents Act, created a sui generis system of protection for agricultural innovations, confining protection to asexually reproduced plants, because of the view that sexually reproduced varieties lacked stability.[1] The section also excluded tuber-propagated plants principally because of a concern that this would lead to monopolies in basic foodstuffs such as potatoes.[2] Applicants for Plant Patents were required to asexually reproduce the plant in relation to which protection was sought to demonstrate the stability of the characteristics of the plant which were claimed. Section 161 required that new varieties be "distinct". The statute did not define this requirement, although the Senate Committee report accompanying the Act, stated that "in order for a new variety to be distinct it must have characteristics clearly distinguishable from those of existing varieties" and that it was not necessary for the new variety to constitute "a variety of a new species".[3]

Legislation, similar to the Plant Patents Act was adopted in Cuba, 1937; South Africa, 1952 and the Republic of Korea, 1973.

2. Plant Variety Rights Protection

2.1 Development of Sui Generis Plant Variety Rights Protection

As with other categories of intellectual property, a key role in the inclusion of agricultural innovations within the international regulatory regime was played by industry associations. The Congrès pomologique de France, held in 1911, had called for special protection for plant

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1 See S.B. Williams, 'Intellectual property Aspects of Plant Variety Genetic Engineering: View of an American Lawyer' UPOV, *Genetic Engineering and Plant Breeding*, 1983, 23.

2 Senate Report accompanying S.4025, Report No. 315, 71st Cong., 2d Sess.

3 *Ibid*., cited by J. Rossman, 'The Preparation and Prosecution of Plant Patent Applications' (1935) J. Patent Office Society 632.

varieties. The International Union of the Horticultural Profession, also considered the matter at its Congresses in Luxemburg (1911), London (1912) and Ghent (1913). The International Institute of Agriculture in its 1927 Congress had stated that the protection of a denomination was insufficient and that a way had to be found to require "any grower who engaged in reproduction of those breeds for the purposes of sale to pay a royalty to the producer".[4] The International Federation of Breeders of Staple Crops had in its 1931 conference, expressed the hope that the legal status of new varieties be assimilated to that of industrial inventions. Discussions concerning the creation of a new organization to agitate for the promulgation of an international legal regime for the protection of plant varieties, occurred at the meetings of the International Breeders' Congress at Leeuwarden in 1936 and the 1937 Conference of the International Organization of Agricultural Industries, also held in the Netherlands. The direct result of these discussions was the foundation in Amsterdam on 17 November 1938, of the International Association of Plant Breeders for the Protection of Plant Varieties (ASSINSEL). The first ASSINSEL Congress, held in Paris on July 8 and 9, 1939 adopted a three-point resolution:

(i) To accept internationally the filing of trademarks and appellations as a means of protection (pending introduction of a patent);
(ii) To adopt the principle of a licence, to be drawn up by ASSINSEL for the purposes of multiplication and sale; and
(iii) To accept internationally the definition of the word 'original' [as] seed produced, offered or sold by the breeder of the variety or under his control by his licensees or successors in title.

The Second World War interrupted these developments. At its Semmering Congress in June 1956 a resolution of ASSINSEL called for an international conference to promulgate an international system for the protection of plant varieties. The French Government had been approached by ASSINSEL, because it had indicated a favourable attitude. On 22 February 1957, the French Government issued invitations to 12 Western European countries[5] to attend a diplomatic conference in Paris Conference from May 7 to 11, 1957 to consider establishing an international regime for the protection of plant varieties. Participation was limited by the French to those states who were known to have similar concerns to it on this subject. The conclusions of the 1957 Conference were set down in its Final Act, adopted on May 11, 1957. This recognised the legitimacy of breeders' rights and established as the preconditions for protection, that a variety had to be distinct from pre-existing varieties and sufficiently homogenous and stable in its essential characteristics. It defined the rights of the breeder and acknowledged the principle of the independence of protection. Following three meetings of the Drafting Committee and two meetings of Committees of Experts, the second session of the Conference was held in Paris from 21 November to 2 December, 1961. An International Convention for the Protection of New Varieties of Plants (UPOV) was presented for the Consideration of the Conference. Article 4(1) applied the Convention to "all botanical genera and species", but it was envisaged that the Convention would have a gradual introduction. A

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4 Quoted in UPOV, 'The History of Plant Variety Protection' in The First Twenty-five Years of the International Convention of the Protection of New Varieties of Plants, UPOV, Geneva, 1987, 80

5 Ie Austria, Belgium, Denmark, Finland, Federal republic of Germany, Italy, the Netherlands, Norway, Spain, Sweden, Switzerland and the UK.

list of 13 genera was annexed to the Convention: wheat, barley, oats or rice, maize, potato, peas, beans, Lucerne, red clover, ryegrass, lettuce, apples, roses or carnations. Article 4(3) required each member State on entry into force of the Convention to apply it to at least five genera from this list and within eight years to all the listed genera.

Article 27 of the 1961 Convention provided for its periodic review, with the first revision scheduled for 1972. Within the first 19 years of its life, the UPOV Convention had attracted the accession of only 12 States. A reason which was identified for the reluctance of States to adopt the Convention was the stringency of its provisions, in particular the obligation of states to select either patent or UPOV-style protection for plant varieties. Article 2 of the Convention was amended to permit the accession of countries like the USA, which had laws allowing or the double protection of varieties under patent and sui generis laws. The list of genera, annexed to the 1961 Convention was removed. This list had contained mainly species from temperate climates. Under the new Article 4, member states agreed to apply the Convention to at least five genera or species, rising to 24 genera of species within eight years. Additionally a grace period was introduced, to permit the marketing of varieties 12 months prior to an application for plant variety protection being made.

A further broadening of the UPOV Convention occurred with the 1991 Revision. The 1991 Act requires states to protect at least fifteen plant genera or species upon becoming members of the Act, and to extend protection to all plant varieties within ten years (Article 3(2)). In response to demands from breeders in industrialized counties, the 1991 Act removed the prohibition against dual protection. The 1991 Act recognized the right of breeders to use protected varieties to create new varieties. However, this exception is itself restricted to such new varieties as were not "essentially derived" from protected varieties (Articles 14(5), 15). The drafters added this restriction to prevent second generation breeders from making merely cosmetic changes to existing varieties in order to claim protection for a new variety. The concept of essential derivation has proved highly controversial in practice, however. Breeders have been unable to agree on a definition of the minimum genetic distance required for second generation varieties to be treated as not essentially derived from an earlier variety and thus outside of the first breeder's control.[6]

From the perspective of farmers, probably the most contentious aspect of the 1991 Act was the limitation of the farmers' privilege to save seed for propagating "on their own holdings" the product of the harvest which they obtained by planting a protected variety "on their own holdings", "within reasonable limits and subject to the safeguarding of the legitimate interests of the breeder" (Article 15(2)). Unlike the 1978 Act, the 1991 version of the farmers' privilege does not authorize farmers to sell or exchange seeds with other farmers for propagating purposes. This is criticized as inconsistent with the practices of farmers in many developing nations, where seeds are exchanged for purposes of crop and variety rotation.[7]

A number of developing countries have resisted the adoption of the 1991 Act as the standard for plant variety protection laws. The foreign ministers of Organization for African Unity

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6 See L. Helfer, *Legal Study on Intellectual Property Rights in Plant Genetic Resources*. FAO, Rome, 2001. para.1.1.1.4.

7 D. Leskien, and M. Flitner, 'Intellectual Property Rights and Plant Genetic Resources: Options for a sui generis system'. (1997) No 6, *Issues in Genetic Resources*, Rome, IPGRI, 60.

issued a statement at a January 1999 meeting calling for a moratorium on IPR protection for plant varieties until an Africa-wide system had been developed that granted greater recognition to the cultivation practices of indigenous communities.

2.2 Plant Variety Rights Protection and the TRIPS Agreement 1994

Probably the most notorious requirement of the TRIPS Agreement is that in Article 27.3(b) which 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 8 of the Agreement, in enunciating the principles which are to animate it, provides that "consistent with the provisions of the Agreement, signatories may "adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development". It would not be too difficult to construct an argument that the obligation to protect plant varieties might be inconsistent with food security. However, the opening words of Article 8 suggest that in a conflict between these provisions, the obligations within the Agreement, such as Article 27.3(b) are paramount.

The application of Article 27.3(b) has arisen as an incident to the review of article by the Council on TRIPS, which commenced in 1999. At the 23 March 2001 meeting of the Council, the Chairman set out a list of key issues which had arisen in the review of Article 27.3(b).[8] These were:

- the link between Article 27.3(b) and development;
- technical issues relating to patent and plant variety protection under article 27.3(b);
- technical issues relating to the *sui generis* protection of plant varieties;
- ethical issues relating to the patentability of life-forms;
- the relationship to the conservation and sustainable use of genetic material; and
- the relationship with the concepts of traditional knowledge and farmers' rights.

The concluding words of Article 27.3(b) envisaged its review by the Council for TRIPS by the end of 1999. A *Communication* to the WTO from Kenya, on behalf of the African Group, to assist the Preparations for the 1999 Ministerial Conference, pointed out the review would pre-empt the outcome of deliberations in other related fora such as the Conference of parties of the Convention on Biological Diversity (CBD), UPOV, FAO, and the OAU (which had developed a model law on Community Rights and Control of Access to Biological Resources). The African Group proposed that an additional five years be allowed, prior to the review of Art.27.3(b). The communication suggested 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;

[8] WTO Doc., IP/C/M/26

> (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."

This African proposal is reflected in part in the Doha Ministerial Declaration of November 2001, which in Clause 19 provided:

> 19. We instruct the Council for TRIPS, in pursuing its work programme including under the review of Article 27.3(b), the review of the implementation of the TRIPS Agreement under Article 71.1 and the work foreseen pursuant to paragraph 12 of this Declaration, to examine, *inter ali*a, 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. In undertaking this work, the TRIPS Council shall be guided by the objectives and principles set out in Articles 7 and 8 of the TRIPS Agreement and shall take fully into account the development dimension."

The Doha Ministerial had set the deadline of December 2002 within which the review, referred to in Clause 19 of the Doha Declaration had referred, was to be finalised and reported to the Trade Negotiations Committee (TNC) "for appropriate action". However, after Doha, the discussions in the TRIPS Council were dominated by the consideration of the public health and patenting issue and the question of plant variety protection under Article 27.3(b) was somewhat neglected. However, in anticipation of the Cancun Ministerial, Morocco, on behalf of the African Group of countries made a Joint Communication to the Council for TRIPS, on 20th June 2003, in an endeavour to finalise the longstanding issues relating to the review of Article 27.3(b) (i) indicating the solutions that the African Group considered needed to be found; (ii) setting out possible areas of agreement on issues that have arisen; (iii) providing suggestions on how to resolve issues on which members had not been able to reach a common understanding.[9]

The Joint Communication asserted that the requirement to protect plant varieties should not in any manner undermine, but should support, the right of Members to protect important public policy goals relating to food security, nutrition, the elimination of rural poverty, and the integrity of local communities. It noted that "the protection of genetic resources and traditional knowledge particularly those originating from developing country Members, is an important means of addressing poverty and is rightly a matter of equity and due recognition for the custodians of the genetic resources and the traditional knowledge." Notwithstanding the efforts to deal with the protection of genetic resources and traditional knowledge in other fora, which are outlined below, the Joint Communication stated that this protection would not be effective "unless and until international mechanisms are found and established within the framework of the TRIPS Agreement." Other means, such as access contracts and data bases for patent examinations, were thus conceived to be supplementary to such international mechanisms, "which must contain an obligation on Members collectively and individually to prohibit, and to take measures to prevent, the misappropriation of genetic resources and traditional knowledge."

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9 WTO Doc., IP/C/W/404, 20 June 2003.

Areas of agreement identified by the African Group, were:

(a) Members have the right and the freedom to determine and adopt appropriate regimes in satisfying the requirement to protect plant varieties by effective *sui generis* systems. Thus the African Model Legislation on the Protection of the Rights of Local Communities, Farmers and Breeders and the Regulation of Access to Biological Resources, was cited as one example of a *sui generis* system, which had been developed to provide appropriate and effective protection for the rights and knowledge of farmers, as well as indigenous peoples and local communities, in a manner that suits the circumstances of Africa and possibly other developing country Members.

(b) Regardless of what *sui generis* system that is adopted for protecting plant varieties, non commercial use of plant varieties, and the system of seed saving and exchange as well as selling among farmers, are rights and exceptions that should be ensured as matters of important public policy to, among other things, ensure food security and preserve the integrity of rural or local communities. The legitimate rights of commercial plant breeders should be protected, but balanced against the needs of farmers and local communities, particularly in developing Members. Any sui generis system should enable Members to retain their right to adopt and develop measures that encourage and promote the traditions of their farming communities and indigenous peoples in innovating and developing new plant varieties and enhancing biological diversity.

(c) Both the TRIPS Agreement and the Convention on Biological Diversity as well as the International Treaty on Plant Genetic Resources should be implemented in a mutually supportive and consistent manner. In this regard, Members retain the right to require, within their domestic laws, the disclosure of sources of any biological material that constitutes some input in the inventions claimed, and proof of benefit sharing.

(d) Traditional knowledge and inventions of local communities should be protected under appropriate regimes, on the understanding that the TRIPS Agreement provides only minimum standards and does not prevent Members from adopting additional areas of protection. In this regard, it is important to develop mechanisms for ensuring equity in relation to the use of genetic resources and traditional knowledge through appropriate international arrangements and mechanisms to supplement domestic laws and measures.

(e) It is important to identify and document genetic resources and traditional knowledge as a way of assisting searches and examinations for novelty and inventive step, and equally important as a mechanism for ensuring equity and promoting economic and social development in the use of genetic resources and traditional knowledge.

Areas that were identified as those where delegations had not reached a common understanding concerned the possibility under Article 27.3(b) for members to grant patents on micro-organisms and on non-biological and micro-biological processes for the production of plants or animals. The African Group's view was that "the distinction drawn in Article 27.3(b) for micro-organisms, and for non-biological and microbiological processes for the production of plants or animals, is artificial and unwarranted, and should be removed from the TRIPS Agreement, so that the exception from patentability in paragraph 3(b) would cover: "plants, animals, and micro-organisms, as well as essentially biological processes and the non-biological and microbiological processes for the production of plants or animals."

Another area without common understanding concerned the international mechanisms that should be adopted within the framework of the TRIPS Agreement to protect genetic resources and traditional knowledge. This was considered to be particularly important because of instances of biopiracy which had occurred. The African Group recommended a combination

of access contracts to regulate the activities of researchers and other gatherers and the use of databases of traditional knowledge by patent offices, in examining patent claims to determine whether they meet the requirements of novelty, inventiveness and usefulness. The Joint communication noted that the construction of these databases was ongoing and that in applying the test of prior art certain domestic laws do not recognise certain (unwritten) forms of traditional knowledge. Also it noted the expense for local communities and some developing Members to seek remedies in overseas courts.

Although the African Group noted the work which was being undertaken in WIPO in this area, the Joint Communication stated that the WIPO initiative might not be relevant and that it was proceeding very slowly.

Consequently, the African Group suggested that the Council for TRIPS should consider adopting a Decision on Protecting Traditional Knowledge as set out in Annex 1 to the communication. This Decision provided:

> 1. This Decision, adopted as a result of the review of Article 27.3(b), shall be an integral part of the TRIPS Agreement.
>
> 2. Rights given effect and to be protected by all Members
>
> (a) Traditional knowledge is a category of intellectual property rights hereby recognised and protected in accordance with this Decision. Members shall protect and enforce rights in respect of traditional knowledge in accordance with the provisions of this Decision. Members may adopt sui generis systems for more extensive protection.
>
> (b) In co-operation with all relevant international and civil society organizations particularly associations of local communities and traditional practitioners, the WTO shall prepare and adopt programmes for the development and review, as may be necessary from time to time, of the protection of traditional knowledge and enforcement of rights conferred under this Decision in respect of traditional knowledge.
>
> (c) The rights relating to traditional knowledge that shall be protected include, in relation to any local community or traditional practitioners, the right for such community or practitioner to:
>
> (i) respect for their will and decisions on whether or not to commercialise their knowledge;
>
> (ii) respect and honour of any sanctity they attach to their knowledge,
>
> (iii) give prior and informed consent for any access and any intended use of their knowledge,
>
> (iii) full remuneration for their knowledge,
>
> (iv) prevent third parties from using, offering for sale, selling, exporting, and importing, their knowledge and any article or product in which their knowledge is input, unless all the requirements under this Decision have been met.
>
> (d) The existence of traditional knowledge in any form or at any stage shall defeat the novelty and inventiveness requirements for purposes of patents and originality for purposes of copyrights under any laws of all Members.
>
> (e) Where:
>
> (i) traditional knowledge has been a lead to the invention,

(ii) any invention that qualifies for patentability has derived at any stage from traditional knowledge,

(iii) any invention is based on in situ genetic resources of any Member,

then, no intellectual property rights shall be granted or protected in any Member unless the requirements on access to genetic resources under the Convention on Biological Diversity have been fully complied with.

(f) Members shall require in their laws that any intellectual property rights granted in breach of this Decision shall, without any further requirements as to procedure other than this provision, be cancelled forthwith. No intellectual property rights shall be granted or protected without due recognition of the traditional knowledge involved in accordance with this Decision. In accordance with this paragraph, Members shall provide for the ex-officio cancellation of any intellectual property rights that breach this Decision.

4. Documentation of Traditional Knowledge and Local Communities

(a) Members may document traditional knowledge in their territories and designate a competent authority to continually carry out this exercise. Members may also maintain registers of local communities and traditional practitioners for administrative purposes, but non-registration shall not prejudice the rights of any local community or traditional practitioner under this Decision.

(b) Members may make appropriate arrangements for the establishment and maintenance of electronic and other registers on traditional knowledge that shall be public documents subject to reasonable regulations they may put in place, and for applications from any local communities or traditional practitioners to the competent authority to register their traditional knowledge.

(c) Local communities and the competent authorities shall have an exclusive right in perpetuity to any information that is documented or entered in the register, to prevent any access or use they have not expressly authorised or any application that is inconsistent with the rights of local communities and traditional practitioners under this Decision.

5. Institutional Arrangements

(a) The Committee on Traditional Knowledge and Genetic Resources is hereby established.

(b) Its functions shall include:

(i) developing and reviewing this Decision and any other instruments,

(ii) overseeing and making recommendations on the protection of traditional knowledge and enforcement of the rights of the Members,

(iii) following activities and developments in relevant regional and international intergovernmental organizations,

(iv) providing forums for dialogue on traditional knowledge, and

(v) conducting studies and making recommendations to Members and relevant organizations on protection of traditional knowledge under the provisions and within the framework of other international and regional instruments.

(c) Every Member shall establish a competent authority and a central enquiry point to provide information and carry out designated functions arising from this Decision.

6. Meaning

(a) Traditional knowledge includes, but is not to be limited to, knowledge systems, innovations and adaptations, information, and practices of local communities or indigenous communities as understood within the territory of the Member, relating to any type of medicine or cures, agriculture, use and conservation of biological material and diversity, and any other aspect of economic, social, cultural, aesthetic or other value.

(b) Traditional knowledge is not static but continues to evolve, and its nature relates to the manner it develops rather than to its antiquity.

(c) For purposes of this Decision, traditional knowledge includes folklore unless the context requires otherwise or it is provided otherwise; and local communities includes indigenous peoples subject to definitions that Member may adopt within their domestic laws.

Where, where the views of delegations suggest a common understanding, the African Group urged the Council for TRIPS to agree upon a Decision and report its adoption to the TNC, whereupon it would immediately become operational. For those areas where there was no common understanding, the African Group urged the Council for TRIPS to focus on the draft Decision on protecting traditional knowledge and the amendment to paragraph (b) to prohibit patents on life forms as a basis for further discussion.

3 Plant Variety Rights Protection and the Availability of Genetic Resources for Breeding

Plant breeders and other supporters of UPOV tend to stress the necessity of being able to freely access genetic material including that which is IPR protected. This is why the UPOV Convention contains such a broad breeders' exemption. Patent law tends to have a much narrower research exemption which is often limited to non-commercial scientific or experimental use. Moreover, while a protected plant variety is covered by a single title, plant-related biotechnological inventions are likely to be protected by a patent and in some cases several patents. The patents may cover not just plants, but also seeds, genes and DNA sequences. The effect of patents is to restrict access to the patented 'products'. It has been argued that 'locking up' genetic resources with patents is a bad thing because innovation in plant breeding is cumulative and depends on being able to use as wide a stock of material as possible. It was to deal with this concern that the FAO International Treaty introduced a number of provisions as were laid out above.

However, apart from patents, the restrictions on access to breeding material may have other causes than IPRs. For one thing, some countries have chosen to except certain categories of plant genetic resources they consider to be strategically important from the multilateral system to be set up under the International Treaty. Also, some developing countries have been exercising their rights under the CBD to regulate access to their genetic resources and in doing so have restricted their free flow. This may well be detrimental to long-term food security even in their own countries.[10]

But beyond these issues about how specific intellectual property rights privatise genetic material needed for breeding is the association of IPRs with the privatisation of agricultural

[10] C. Fowler, 'Sharing agriculture's genetic bounty' (2002) 297 *Science* 157.

research, the shrinkage of non-proprietarian public sector research, and the increased concentration of ownership of breeding material, research tools and technologies in the hands of a small number of giant corporations.[11] Not only does this trend reduce the free circulation of breeding material, but it can also make public policy making aimed at enhancing food security harder to put into practice. This is because it is much more difficult for governments to influence companies than the public institutions they partly or wholly fund.

4. Patents on Plants, plant varieties, seed and other propagating material

As was mentioned above, Plant Variety Protection laws were developed in response to industry calls for sui generis protection for agricultural and horticultural innovation. The inclusion of a seed saving exception for farmers, was a public policy safeguard which was an early reflection of food security concerns. This safeguard does not exist in patent statutes and this absence was an inducement for seed companies to shift their attention to the patent system as a means of protecting their innovations. This attention shift coincided with the development of modern biotechnologies.

Patent protection was not originally considered to be a particularly effective system for the protection of plant varieties. Prior to the development of modern biotechnology, the breeding of a new variety could not be said to involve an inventive step and such innovations as were made, could be considered to be obvious rather than inventive. However with the extension of patent protection to recombinant methods for producing transgenic plants and the resulting products, patents have begun to assume an increasing significance in plant variety protection. The broader ambit of patent rights is a particular advantage of this form of intellectual property protection, covering, as it does, plants, seeds and enabling technologies. PVRs are highly specific to the variety and their scope is limited by reference to the physical (propagating) material itself, combined with the description of the variety given in the documentary grant of the rights

The basis for the patentability of biotechnological innovations was the 4:3 decision of the US Supreme Court patentability of living microorganisms was allowed by the Supreme Court in in *Diamond* v *Chakrabarty*[12] which concerned the development of a bacterium genetically engineered to degrade crude oil. The basis of the Supreme Court's decision was that new microorganisms not found in nature were "manufacture" or "composition of matter" within the meaning of s.101 of the US Patent Act and were thus patentable. The general approach which patent offices have taken, following the approach in *Diamond* v *Chakrabarty*, is that gene-sequences are inventions when they have been isolated and purified. A number of patent offices in developed countries have permitted the patenting also of partial DNA sequences and Expressed Sequence Tags (ESTs). The value of the patented invention regarding DNA (isolation or synthetization) lies in the encoded information programming the production of a protein or other substances.

In Europe the Directive on the Legal Protection of Biotechnological Inventions specifically provides in Article 3.2 that "Biological material which is isolated from its natural environment

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11 See R.W Herdt, 'Enclosing the global plant genetic commons'. Paper prepared for delivery at the China Center for Economic Research, May 24,1997.

12 447 US 303 (1980).

or produced by means of a technical process may be the subject of an invention even if it previously occurred in nature".

Article 53(b) of the European Patent Convention (EPC) excludes plant varieties, as well as "essentially biological processes" from the scope of patentable subject matter. This raises, in the first instance, the definitional distinction between plants and plant varieties. The UPOV Convention defines plant variety in terms of a plant grouping within a single biological taxon of the lowest known rank, which grouping can be:

> defined by the expression of characteristics (such as shape, height, colour and habit) resulting from a given genotype or combination of genotypes;
> distinguished from any other plant grouping by the expression of at least one of the said characteristics; and
> considered as a unit with regard to its suitability from being propagated unchanged

The first consideration of the distinction between plant and plant variety by the Technical Board of Appeal of the European Patent Office (EPO) occurred in 1984 in the *Ciba/Geigy* determination.[13] This concerned a plant which had been treated with a chemical compound to confer on the plant a degree of protection from the toxic side-effects of certain herbicides. The Examination Division had refused the patent application on the basis of Art.53(c). This was reversed by the Technical Board of Appeal, which, applying the definition of plant variety in the UPOV Convention, stated that "Article 53(c), "prohibits only the patenting of plants or their propagating material in the genetically fixed form of the plant variety…Plant varieties in this sense are all cultivated varieties, clones, lines, strains and hybrids".[14] In this case the claims covered merely the application of a chemical treatment and not plant varieties as such.

This approach was applied by the Technical Board of Appeal in the *Lubrizol (Hybrid Plants)* case[15] where the Board held that "the term 'plant varieties' means a multiplicity of plants which are largely the same in their characteristics (i.e. homogeneity) and remain the same within specific tolerances after every propagation or every propagation cycle (i.e. 'stability')"[16] The Board then ruled that as the hybrids in issue were not stable, they did not fall within the excluded category of plant varieties.

The European Biotechnology Directive permits the patentability of inventions concerning plants, where "the technical feasibility is not confined to a particular plant…variety".[17] Patent claims can therefore be made in respect of plant groupings, or as stated in Recital 31 to the Directive,

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13 Case T 49/83 [1984] *O.J. EPO* 112.
14 *Ibid.*, at 114-115.
15 Case T320/87 [1990] *O.J EPO* 71.
16 *Ibid* at 79.
17 *Directive on the Legal Protection of Biotechnological Inventions*, Article 4(1) para.2, 98/44/EC [1998] *O.J.* L213/130.

> Whereas a plant grouping which is characterized by a particular gene (and not its whole genome) is not covered by the protection of new varieties and is not excluded from patentability even if it comprises new varieties of plants.

This qualification was addressed by the Technical Board of Appeal in *Novartis/Transgenic Plant*.[18] The application concerned a patent containing claims to transgenic plants comprising in their genomes specific foreign genes, the expression of which resulted in the production of antipathologically active substances, and to methods of preparing such plants. The EPO had denied registration, supported by the Technical Board of Appeal, on the ground that art.53(b) denied the patentability of an invention which could embrace plant varieties.

In its decision of 20 December 1999, the Enlarged Board of Appeal indicated that it would favour the application because, in substance, it did not involve an application for a plant variety. This determination contains some useful guidance on the legal definition of plant varieties. The Enlarged Board of Appeal noted that the definitions of plant variety in the UPOV Convention and the EC Regulation on Community Plant Variety Rights refer to "the entire constitution of a plant or a set of genetic information", whereas a plant defined by a single recombinant DNA sequence "is not an individual plant grouping to which an entire constitution can be attributed". It observed that the claimed transgenic plants in the application before it were defined by certain characteristics which allowed the plants to inhibit the growth of plant pathogens. No claim was made for anything resembling a plant variety. The tribunal noted that in the case of PVR an applicant had to develop a plant group, fulfilling in particular the requirements of homogeneity and stability, whereas in the case of a typical genetic engineering invention, a tool was provided whereby a desired property could be bestowed on plants by inserting a gene into the genome of a specific plant. It observed that the development of specific varieties was not necessarily the objective of inventors involved in genetic engineering.

Outside Europe the prohibition against the patenting of plant varieties is absent. In the USA for example, the Federal Circuit resolved any potential conflict between patent protection and protection under the Plant Variety Protection Act in its decision in *Pioneer Hi-Bred International Inc. v. J.E.M. Ag Supply Inc*.[19] The defendants objected that Pioneer had obtained both patent protection and certificates of protection under the Plant Variety Protection Act for the same seed-produced varieties of corn. The defendants argued that the enactment of the Plant Variety Protection Act had removed seed-produced plants from the realm of patentable subject matter the Patents Act. The Federal Circuit rejected this argument noting that the Supreme Court held that "when two statutes are capable of co-existence, it is the duty of the courts . . . to regard each as effective".

The Joint Communication of the African Group to the TRIPS Council[20] suggested that Article 29 of the TRIPS Agreement seems to be the most suitable for an appropriate modification to deal with the issue of patenting plant variety rights, by including the requirements for equity, disclosure of the community of origin of the genetic resources and traditional knowledge, and a demonstration of compliance with applicable domestic

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18 [2000] *O.J. EPO* 511.

19 200 F.3d 1374 (Fed. Cir. 2000), *cert. granted,* 148 L. Ed. 2d 954 (2001)

20 WTO Doc., IP/C/W/404, 20 June 2003.

procedures. Thus the Group suggested that Article 29 be modified by adding the following as paragraph 3:

> 3. Members shall require an applicant for a patent to disclose the country and area of origin of any biological resources and traditional knowledge used or involved in the invention, and to provide confirmation of compliance with all access regulations in the country of origin.

5. Conservation of Biological Diversity and Food Security

Until the 1980s, few if any people considered IPRs to have anything whatsoever to do with genetic erosion. This is not the case now. Critics maintain that IPRs provide perverse incentives which encourage activities that are prejudicial to biodiversity. Are they right? One way to investigate this issue is to frame it in the form of three sets of questions:

1. Do intellectual property rights encourage the spread of monocultural agriculture? And if so, does this cause erosion of biodiversity?
2. Do plant variety rights encourage the breeding of genetically uniform varieties and the use of a relatively small pool of genetic material? And if either of these is the case, is it prejudicial to biodiversity?
3. Is the increasing production and sale of seed-agrochemical 'packages' (such as transgenic crops sold with pesticides and/or herbicides for which they have built-in resistance) harmful to biodiversity? And if so, are IPRs an inducement for companies to produce these kinds of 'package'? In other words, is this an IPR issue?

5.1 IPRs and monocultures

With respect to the first set of questions, one of the most plausible critiques of IPRs is by Reid (1992), who identifies a strong connection between IPRs and a bias towards centralised research, and believes that this has an impact on agro-biodiversity. He finds that the prevailing policy framework for the use of genetic resources for food and agriculture favours 'centralised crop breeding and the creation of uniform environmental conditions, and discourages agro-ecological research or local breeding tailored to local conditions.' IPRs enhance incentives to develop seeds that will have a large potential demand. To ensure maximum demand for their products, the seed companies will tend to focus their research on commonly utilised high-value crops and develop varieties that can be cultivated as widely as possible. To do so means either breeding through selection of genes for maximum adaptability, or introducing the new seeds while also promoting farming practices that reduce environmental heterogeneity. The biodiversity-erosive effects of this IPR-supported bias towards centralised crop breeding programmes are: (i) decreased crop diversity; (ii) decreased spatial genetic diversity; (iii) increased temporal genetic diversity due to the need to replace cultivars with new ones every few years; and (iv) increased use of external inputs.

It is important to point out that monocultural agricultural systems are not inherently biodiversity-erosive. It is true that they may cause biodiversity loss if they replace more biologically-diverse ecosystems. But *if* a monocultural system produces higher yields per harvest and/or more harvests per year compared to a more polycultural agro-ecosystem it

replaced, pressure to open up biologically-diverse ecosystems to cultivation *may* be reduced as a consequence.

Kothari and Anuradha[21] conclude that IPRs alone cannot be held responsible for the loss of agro-biodiversity, but that IPRs are bound to encourage the displacement of a wide diversity of traditional local varieties in favour of a small number of widely adapted hybrids and homogeneous modern varieties. Moreover, they point out that one of the lessons of the Green Revolution is that the development of new varieties by the seed industry is unlikely to match the loss of traditional varieties after these new varieties are introduced.

However, the erosion of biodiversity will not necessarily result from the spread of monocultural systems. If a monocultural system produces higher yields per harvest and/or more harvests per year compared to a more polycultural agro-ecosystem it replaced, pressure to open up biodiverse ecosystems to cultivation *may* be reduced as a consequence (though the opposite result is also possible). It is important also to point out though that this trend in crop breeding dates back to when the Green Revolution began, and earlier still in some countries. The varieties most commonly associated with the Green Revolution were developed by public crop breeding institutions, not corporations. On the face of it, this suggests that this may not be an IPR-related problem at all.

According to a preliminary study produced for the Secretariat of the CBD for consideration of the 3rd meeting of the COP[22], other policies that might encourage the use of new crop varieties and the loss of landraces include: (a) government farm credits and subsidies, and extension services; (b) the policies and programmes of international agencies and donor institutions; (c) the marketing and research and development policies and programmes of transnational corporations; and (d) the increasingly concentrated corporate control of pesticide and agro-biotechnology research and distribution.

The Leipzig Declaration on conservation and sustainable utilisation of plant genetic resources for food and agriculture, adopted by the International Technical Conference on Plant Genetic Resources on 23 June 1996 stated that plant genetic resources for food and agriculture (PGRFA) should be conserved as "the basis of natural and directed evolution in the plant species most critical to the survival and well being of human beings. All countries require plant genetic resources if they are to increase food supplies and agricultural production sustainably and meet the related challenges of changes in the environment, including climate change"

5.2 PVP and genetic uniformity

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21 A. Kothari and R V Anuradha, Biodiversity, intellectual property rights, and GATT Agreement: how to address the conflicts? (1997) 32 *Economic and Political Weekly* 2814.

22 Convention on Biological Diversity Secretariat, *The impact of intellectual property right systems on the conservation and sustainable use of biological diversity and on the equitable sharing of benefits from its use. A preliminary study. Note by the Executive Secretary* [(1996) UNEP/CBD/COP/3/22.

Rangnekar has argued that PVP encourages plant breeding based upon existing material already in scientific use, while providing 'juridical legitimization to the breeding of genetically uniform varieties'.[23] On what basis may such claims be credible?

Let us consider first the point that PVP encourages the use of a narrow pool of germplasm by crop breeders. What makes such a claim plausible is the breeders' exemption, which, since it permits free use of plant genetic resources already in circulation, does little to encourage the discovery and input of resources that may exist in the fields of traditional cultivators and other types of ecosystem characterised by relatively high levels of biodiversity. Defenders of PVP may counter that the number of varieties introduced into European and Northern markets is probably greater than it would have been without the incentive of a PVP system. On the other hand, an increased quantity of plant varieties being cultivated does not necessarily mean that agro-biodiversity is greater than would otherwise exist in farmers' fields. This is because new varieties tend to be based on the recombination of genes acquired from a fairly limited gene pool shared by plant breeders, who generally do not claim exclusionary rights over discovered genes or plants into which they are inserted. Furthermore, Rangnekar claims that PVP rights encourage breeders to adopt strategies of planned obsolescence 'to reduce the durability of plant varieties so as to induce regular replacement purchases by farmers'. He claims some empirical evidence that UK wheat breeders do adopt such strategies.

One of the principal causes which has been identified for the loss of diversity in crops is the replacement of local varieties by improved varieties and species, which do not contain the diverse genetic endowment of the traditional farmers' varieties. Genetic erosion has been reported in both developing and developed countries. For example the FAO reports that only 20 % of the local Mexican maize varieties 1930 are now known, similarly, in China, wheat varieties have decreased by a factor of 10 between 1949 and 1970.[24]

5.3 IPRs and crop-agrochemical linkages

With respect to the second set of questions, it is true that seed companies often develop hybrids and other modern varieties that depend upon applications of agrochemicals (such as fertilisers, herbicides and insecticides) to achieve high yields. A common accusation is that excessive use of these chemicals is encouraged and other plants growing nearby are killed as a result. However, IPRs are unlikely to be directly responsible for this trend in crop breeding, which dates back to the time when the Green Revolution began, and earlier still in some countries. The Green Revolution is frequently blamed for the development and spread during the 1950s and 1960s of high-yielding wheat and rice varieties requiring heavy applications of agrochemicals, but the varieties most commonly associated with the Green Revolution were developed by public crop breeding institutions and were not IPR protected.

However, the IPR link appears stronger in the case of genetically modified crops. In recent years, life-science corporations (often originally chemical companies that have bought seed companies) have increasingly been creating transgenic plants with built-in resistance either to

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[23] D. Rangnekar, 'R&D appropriability and planned obsolescence: empirical evidence from wheat breeding in the UK (1960-1995)' (2000) 11(5) *Industrial and Corporate Change* 1011.

[24] FAO, The State of the World's Plant Genetic Resources for Food and Agriculture, Rome, FAO 1998, 35.

herbicides marketed by the same company[25] (see Bell 1996; Kloppenburg 1988) or to insect pests. In the former case, both the herbicide and the seed for which it is designed are likely to be patent-protected. For example, Monsanto had made enormous profits from one of its patented agrochemicals, a glyphosate-based herbicide marketed under the name of Roundup, and was concerned to ensure that once the patent expired, it would not face too drastic a shortfall in revenues as competing producers of the same herbicide entered the market. Monsanto turned to biotechnology for a solution. The company developed and patented transgenic soybeans, canola, cotton and corn containing a gene providing resistance to its Roundup. Monsanto's patents protect the gene for Roundup resistance and all plants containing it, and these have several more years to run. As farmers who buy these 'Roundup Ready' seeds are contractually obliged to purchase Monsanto's patented herbicides, sales of the seeds are good for sales of the herbicides and vice versa. It is unclear, however, that this strategy will work in the long term. Roundup Ultra went off patent in 2000 and farmers may well turn to cheaper versions sold by competitors.

An example of a crop with built-in resistance to a pest (rather than a herbicide or pesticide) is Monsanto's NewLeaf potato, which claims to provide *total* protection against the Colorado beetle (Magretta 1997). Another is Novartis' patented Bt corn, which is designed to resist the European corn borer pest.

The position of the large life-science corporations such as Monsanto and Novartis is that genetic engineering can reduce or even obviate pesticide use. Monsanto's claim is that when they produce packages of herbicides and plants resistant to these herbicides, their aim is not to ensure that farmers will need to increase herbicide use. Their main interest is to ensure that farmers use *their* herbicides. If these are more effective than alternative products, overall herbicide use may decrease. According to the company, 'Roundup herbicide can reduce the number of weed treatments and can also help reduce tillage to conserve soil moisture and reduce erosion of valuable topsoil'.[26]

Environmentalists and some scientists counter that genetically-engineered herbicide resistance has negative environmental effects.[27] Among the claims commonly made are that use of herbicide-resistant transgenic plants may: (a) encourage excessive use of herbicides which may kill other plant varieties and species (Bell 1996); (b) accelerate the development of resistance among pests (Jenkins 1998); and (c) create the possibility of herbicide resistant genes crossing over to other plants including the weeds being targeted. This could create 'superweeds' which would render the herbicide ineffective in the long term, and cause ecological impacts that cannot easily be predicted. It may also be possible that transgenic plants themselves could become 'weeds' if the added characteristic gives them a competitive advantage over neighbouring wild species (de Kathen 1996), though this is unlikely in the case of the most highly domesticated crop species. Some critics also allege that herbicides are far more toxic than the manufacturer companies are willing to admit, and that the health of

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25 See J. Bell 'Genetic engineering and biotechnology in industry'. In: Baumann, M, Bell, J, Koechlin, F and Pimbert, M (eds) *The Life Industry: Biodiversity, People and Profits*. Intermediate Technology Publications, London, 1996, 31 -52; Kloppenburg Jr., J (1988) *First the Seed: The Political Economy of Plant Biotechnology*, Cambridge University Press, Cambridge.

26 Monsanto World Wide Web site (http://www.monsanto.com).

27 For excellent assessments of the environmental impacts of agricultural biotechnology see Lappé and Bailey (1999) and Krimsky and Wrubel (1996).

both farmers and consumers could be affected (McNally and Wheale 1996; Tappeser and von Weizsäcker 1996).

Concerns are also expressed that increased use of hybrids and other modern varieties specifically designed for use with other proprietary agricultural inputs such as fertilisers and pesticides may have serious social impacts, especially in developing countries. These crop-herbicide-pesticide linkages can be considered to represent a shift towards capital intensive agriculture that increases the costs of farming and may therefore be detrimental to small farmers (Verma 1995). Consequently, critics maintain that farmers must have the right to choose whether or not to accept these packages and should not be subjected to aggressive sales promotion campaigns.

Even if we accept that these concerns are well-founded, are IPRs implicated just because plants (where transgenic or not), herbicides and pesticides can be patented? Corporations in these technological fields tend to claim that without IPR protection they would have no incentive to invent or to innovate. This suggests that these products would not exist without IPRs. But this does not mean that the national patent office is the appropriate place to deal with marketing approval for such products. Most countries have an agency with jurisdiction over such matters, and such a body is probably much better placed than the patent office to decide whether plant-herbicide-pesticide packages are in the public interest or not.

In conclusion, there is a dearth of reliable empirical evidence on the IPR-genetic erosion connection. What can be presumed with some certainty is that the loss of agro-biodiversity cannot be attributed to a single cause.

5.7 Food Security and the Convention on Biological Diversity (CBD)

5.7.1 Introduction to the CBD

The Rio Earth Summit, which was convened in June 1992, promulgated the 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 resources[28] and for the "fair and equitable sharing" of the benefits arising from the utilisation of genetic resources[29]. "The single most divisive issue in the negotiations was the relationship between intellectual property rights and access to genetic resources."[30] 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

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

29 CBD, Art.1.

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

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".

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.

5.7.2 Scope of the CBD Access Regime

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.[31] 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.[32]

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.[33] 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.

5.7.3 Sovereign Rights over Genetic Resources (Art 15 (1))

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

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

33 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.

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. This leaves unanswered the ownership issues raised by the creation of the CGIAR germplasm collections.

5.7.4 Mutually Agreed Terms, Prior Informed Consent and Benefit Sharing

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.

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.

At the second Conference of the Parties (COP), held in Jakarta, from November 6 to 17, 1995, a Report including ‘Possible elements of guidelines on mutually agreed terms.’ was tabled.[34] The possible elements which were suggested to Parties for inclusion in access and benefit-sharing arrangements included, *inter alia*, “agreeing on respective *intellectual property rights* over the genetic resources and technologies developed using them.” The fourth COP decided in Decision IV/8 to establish a Panel of Experts with the mandate “to draw upon all relevant sources … in the development of a common understanding of basic concepts and to explore

[34] UNEP/CBD/COP/2/13, Section H, paras 90 to 92.

all options for access and benefit sharing on mutually agreed terms including guiding principles, guidelines, and codes of best practice for access and benefit-sharing arrangements."

The Panel of Experts on Access and Benefit-sharing, at its first meeting, held in San José, Costa Rica, from October 4 to 8, 1999, concluded that one of the "key lessons with respect to promoting mutually agreed terms in access and benefit-sharing arrangements" is that "Contractual agreements, for the moment, are the main mechanism for gaining access to genetic resources and delivering benefits."[35] Considering that transaction costs have a significant impact on actual use of genetic resources, the Panel identified "standardized Material Transfer Agreements" as one of the mechanisms to reduce transaction costs.

> The fifth COP in Decision V/26 decided, *inter alia*, to establish an *Ad Hoc* Open-Ended Working Group on Access and Benefit-sharing with "the mandate to develop guidelines and other approaches for submission to the Conference of the Parties and to assist Parties and stakeholders in addressing the following elements as relevant to access to genetic resources and benefit-sharing, *inter alia*: terms for prior informed consent and mutually agreed terms; roles, responsibilities and participation of stakeholders; relevant aspects relating to *in situ* and *ex situ* conservation and sustainable use; mechanisms for benefit-sharing, for example through technology transfer and joint research and development; and means to ensure the respect, preservation and maintenance of knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity, taking into account, *inter alia*, work by the World Intellectual Property Organization on intellectual property rights issues.

The second Meeting of the Panel of Experts on Access and Benefit-sharing, which met in Montreal, from March 19 to 22, 2001, considered a Note by the Executive Secretary which highlighted certain aspects of developing instruments to assist in the elaboration of fair and equitable contractual arrangements. These included:

> To reduce transaction costs, measures could include standard Material Transfer Agreements and Umbrella Agreements, under which repeat access under expedited arrangements can be made;
> Mutually agreed terms should also include provisions on user obligations;
> Different resources and uses require different contractual arrangements. Therefore, to the extent possible, commercial arrangements should be anticipated at the outset.
> Benefits are often generated from the commercialization of derivatives that use genetic resources as a source of innovation, such as synthesized products. In these instances, for fair and equitable benefit-sharing, it is important that the scope of contracts include the full range of biotechnology applications in addition to biological resources accessed;

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[35] See UNEP/CBD/COP/5/8, paras 50 and 53.

> In order to reflect the increasing role of intermediaries in contractual arrangements and access-permitting mechanisms, a flexible and simple approach to protect the interest of all parties should be elaborated; Parties should be aware of relevant agreements that may pre-date an agreement under development.[36]

In its Report the Expert Panel noted that intellectual property clauses played a fundamental role access and benefit-sharing contracts and that there was "a need for awareness and capacity-building at all levels, as well as a need to develop up-to-date model intellectual property right clauses." and that WIPO might assist in this regard.[37]

6 Food Security and Agricultural Research

The First Green Revolution can be traced back to the work of Norman Borlaug, a US 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 15 international agricultural research centres, which became associated in the Consulting Group for International Agricultural Research (CGIAR).[38] Each of these centres undertakes research into crops, livestock and materials of interest to developing countries. 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. 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.

The international agricultural research centres of the CGIAR were at the forefront of the public agricultural research effort, which until the 1990s represented some 80% of funding for agricultural research. Subsequently, the research expenditures of national research institutes have exceeded that of the CGIAR[39], but more significantly, the investment in agricultural research by private seed companies has increased to about one third of global expenditure.[40] The application of intellectual property rights in agricultural research is the principal explanation for what in effect has become the privatisation of agricultural research. As is discussed below, the creation of intellectual property rights in plant varieties developed

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36 UNEP/CBD/ABS-EP/2/2, para. 37(a)-(g).

37 UNEP/CBD/WG-ABS/1/2, para. 77(d).

38 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).

39 P. Pardey and R. Beintema, "Slow Magic; Agricultural R&D a Century After Mendel", IFPRI, Oct. 26, 201.

40 Ibid., 8.

through classical breeding and the propertisation of genetic resources and associated enabling technologies through innovations in patent law have been the vehicles through which private agro-industrial enterprises have assumed a dominant position in agricultural research.

This development has a number of significant implications for food security. Principal among these are: (i) the research priorities of the private agricultural research sector are not necessarily congruent with the interests of developing countries, particularly in relation to the food crops which are the focus of private research; (ii) enabling technologies and useful genetic materials have increasingly become concentrated in the private sector; (iii) the commercial objective of private agricultural innovators, to secure control over seed germination to oblige farmers to pay for each planting, is inconsistent with the traditional seed-saving practices of farmers; and (iv) the commercial objective of private seed companies has been to encourage mono-cultures based on their proprietary products, which has resulted in a loss of important genetic diversity and in adverse environmental impacts. A related development has been a number of instances of "biopiracy" in which the genetic resources of CGIAR centres have been the basis of intellectual property rights applications by private parties.

> For example, 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 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, Syria. 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). The Australian Plant Breeder's Rights Office did not have an opportunity to make a determination on the registrability of these varieties because the furore caused by these applications led to their withdrawal, prior to determination.

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".[41] 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".[42]

> Research by 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

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41 'Editorial. Lest We Starve', No. 2121, *New Scientist*, 14 February, 1998, 3.

42 Edwards and Anderson, 'Seeds of Wrath', *Ibid*, 14.

ensure that these issues be resolved and the materials in the CGIAR remain in the public domain".[43] 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.[44] 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.

An illustration of the impact of patenting upon the research activities of the CGIAR Centres is provided by an incident arising from the development by the International Rice Research Institute (IRRI) of 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 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, 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 7th 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 (U.S. 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

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43 CGIAR Press Release 'CGIAR Urges Halt to Granting of Intellectual Property Rights for Designated Plant Germplasm', Feb. 11, 1998, http://www.cgiar.org:80/ germrel.htm.

44 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).

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. UC Davis initially sought royalties from IRRI for the use by it or its clients of Xa21. A licence was negotiated with UC Davis to allow non-commercial researchers access to the gene, provided they did not develop commercial products based on that gene. This would have the effect of preventing rice producing countries which used the gene from exporting into the US market. 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."[45]

A particularly egregious example of the propertisation of germplasm relied upon by developing country farmers was the grant by the US Patent and Trademarks Office of a patent (no. 5,894,079) on April 13, 1999 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." Mr Proctor, was the president of a Colorado (USA) based seed company, POD-NERS. 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.[46] According to Miguel Tachna Felix, of the 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 U.S. patent. On 20 December 2000 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.[47] 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. 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. Although, there was no evidence that the patent owner obtained his yellow beans from CIAT's germplasm collection, 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.[48] 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 recognized by the CBD. The USPTO is currently determining this challenge.

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45 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, 13.

46 'Mexican Bean Biopiracy', Biotechnology Notice Board, posted by: PANUPS panupdates@panna.org , January 24, 2000.

47 RAFI, 'Enola Bean Patent Challenged', News Release, 5 January 2001 www.rafi.org.

48 Ibid.

One impact of these biopiracy episodes has been the response of the donor community, which funds the CGIAR Centres to induce them to emulate the private sector and to exploit their biological resources in support of their research mandate. Some CGIAR Centres perceive that Centre-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.[49]

7. International Organizations and Institutions and Access to Genetic Resources

7.1 The FAO International Treaty on Plant Genetic Resources

Plant genetic resources for food and agriculture (PGRFA) were freely exchanged by the international agricultural research institutes of the CGAIR, as well as by their national counterparts on the basis that they were the common heritage of humankind. This principle was embodied in the International Undertaking adopted by the FAO Conference in 1983. The International Undertaking was adopted as a non-binding conference resolution. In subsequent years the principle of free exchange was gradually narrowed by the impact of intellectual property rights upon agriculture. 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 Undertaking. 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". A further resolution in 1991 recognized the sovereign rights of nations over their own genetic resources. Agenda 21, promulgated at the Rio Earth Summit in 1992 called for the strengthening of the FAO Global System on Plant Genetic Resources. Resolution 3 of the Final Act to the CBD noted that the access to *ex situ* germplasm collections, such as those maintained by the CGIAR, and the realization of Farmers' Rights, were the province of the International Undertaking. The 1993 FAO Conference called on member states to harmonize the International Undertaking with the CBD. Negotiations for revision of the International Undertaking to take account of both the CBD and the TRIPS Agreement commenced in November 1994 and was consummated with the adoption of the International Undertaking as the International Treaty on Plant Genetic Resources for Food and Agriculture.

The objectives of the Treaty, are stated in Article 1 to be "the conservation and sustainable use of plant genetic resources for food and agriculture and the fair and equitable sharing of the benefits arising out of their use, in harmony with the Convention on Biological Diversity, for sustainable agriculture and food security".

Article 4 of the Treaty requires signatories "where appropriate" to "promote an integrated approach to the exploration, conservation and sustainable use of plant genetic resources for food and agriculture". Article 10.2 contains the agreement of the Contracting Parties to "establish a multlateral system, which is efficient, effective and transparent, both to facilitate

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

access to [PGFRA] and to share, in a fair and equitable way, the benefits arising from the utilisation of these resources, on a complementary and mutually reinforcing basis". Facilitated access to PGFRA is to be provided in accordance with the conditions prescribed in Article 12.3. Paragraph (d) of this provision provides that the recipients "shall not claim any intellectual property or other rights that limit the facilitated access" to PGFRA, or their "genetic parts or components", in the form received from the Multilateral System. This, of course, does not prevent intellectual property rights being claimed in relation to germplasm which is modified by the recipient.

Article 13.1 recognises that benefits accruing from facilitated access to PGFRA shall be shared fairly and equitably under this Article. Article 13.2 envisages that this sharing of benefits include the exchange of technical information, access to technology, capacity building and the sharing of monetary benefits from commercialisation.

Article 28 provides that the Treaty enters into force, 90 days after accession by 40 countries. Until that date, the International Undertaking will remain operative.

The establishment of the Multilateral System was the principal innovation introduced by the treaty. This asserts the primacy of national sovereignty over biological resources, but in fact imposes limitations on countries on their ability to restrict access to other states. Facilitated access has to be provided to the crops listed in Annex I, which account for a significant part of human nutrition. Member states are obliged to make available all passport data and, subject to applicable law, any other associated non-confidential descriptive information. In relation to material which is under development by farmers or breeders at the time when access is requested, the Treaty gives the country of origin the right to delay access during the period of development. Two compromises were necessary to secure this right of access: first, is the limitation imposed by Article 12 upon recipients seeking intellectual property rights in material obtained under the Treaty; the second was the right of donors to receive some form of benefit sharing. Benefit sharing mechanisms under the Treaty include: the exchange of information, access to and transfer of technology, capacity building, and the sharing of the benefits arising from commercialisation.

The CGIAR Centres had signed agreements with the FAO in 1994, placing the acquisitions to their germplasm collections after that date under the trusteeship of the FAO. Under the Treaty, new agreements were invited, to determine that the access provisions of the Treaty would govern the germplasm collections of the Centres which fell within Annex I list, collected after the entry into force of the Treaty.

7.1.1 Farmers' Rights and Food Security

Article 9 of the International Treaty on Plant Genetic Resources for Food and Agriculture implements the proposal which was developed under the International Undertaking for the recognition of farmers' rights. The policy behind this recognition is stated in Article 9.1, namely that:

> The Contracting 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.

The principal contribution of traditional farmers to agrobiodiversity has been their conservation of landraces, which are crop varieties which are primitive cultivars, developed by local farmers to deal with the local climate and diseases and to cater to local tastes and food-preparation practices.[50] This development may involve the interbreeding of locally occurring undomesticated plants with cultivated plants, as well as the exchange of different genotypes among farmers and farms.[51]

7.1.2 Traditional Knowledge and Food Security

A 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.

The economic value of biological diversity conserved by traditional farmers for agriculture is difficult to quantify. 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" [52] 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.[53]

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50 See S.B. Brush, .ed. *Genes in the Field: On-Farm Conservation of Crop Diversity.* Rome, Ottawa, etc: IPGRI, IDRC, and Lewis Publishers, 2000.

51 See P. Wright, P. 'Intellectual Property and Farmers' Rights' in R. Evenson, D. Gollin and V. Santaniello, Eds. *Agricultural Values of Plant Genetic Resource*s. 1998, Wallingford, CABI.

52 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 Resource*s, Wallingford, FAO/CEIS/CABI, 1998, 228.

53 McNeely, 'Biodiversity and Agricultural Development: The Crucial Institutional Issues' in

[Footnote continued on next page]

Traditional knowledge is particularly important in the development of farming systems adapted to the local conditions, and farming practices. This may enable the utilisation marginal lands, contributing to food security in enabling access to food in remote areas, as in contributing to the management of the environment by, preventing erosion, maintaining soil fertility, and agrobiodiversity.[54]

Article 9.2 of the FAO International Treaty on PGRFA envisages that "the responsibility for realizing Farmers' Rights, as they relate to Plant Genetic Resources for Food and Agriculture, rests with national governments" and that national legislation should include measures relating to: "(a) protection of traditional knowledge relevant to plant genetic resources for food and agriculture". Traditional knowledge has played an important role in assuring food security for subsistence communities. Farmers in subsistence systems have tended to utilise a diverse selection of crop species in order to assure their annual harvests and thus to guarantee a minimal level of production and to prevent food shortage. Seed production in many instances has been on the collection of and domestication of locally known, wild varieties. Modern agricultural practices depend on crop species that promote productivity and resistance to disease that can only be maintained with the continuous input of new germplasm. The diversity of landraces and the associated information on their specific qualities contribute invaluable information to formal breeding processes. It has been noted that the loss of biological diversity is paralled by the loss of traditional knowledge. Where a plant variety becomes extinct, then the entire body of knowledge about its properties is condemned to irrelevancy.

Article 9.2 of the WTO International Treaty on PGRFA envisages that "the responsibility for realizing Farmers' Rights, as they relate to Plant Genetic Resources for Food and Agriculture, rests with national governments" and that national legislation should include measures relating to:

> (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.

Finally, Article 9.3 provides that the Article shall not be interpreted "to limit any rights that farmers have to save, use, exchange and sell farm-saved seed/propagating material".

An assumption of Art. 9.1 is that the landraces used by traditional farmers are a dynamic genetic reservoir for the development of new varieties and for the transmission of desirable genetic traits. The traditional knowledge of local and indigenous communities is similarly perceived. As a means of remunerating these groups for their past contributions to the

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[Footnote continued from previous page]

D.R.Lee and C.B.Barrett, Eds, Tradeoffs or Synergies? Agricultural Intensification, Economic Development and the Environment, Wallingford, CABI, 2001,, 399 at 404.

[54] See

development of plant genetic resources for food and agriculture production, there can be little argument, except about the quantum and distribution of this remuneration.

Inevitably, any calculation of the equitable share, which traditional farmers and indigenous communities might enjoy under a Farmers' Rights, or Traditional Knowledge regime will be arbitrary. However the intellectual property system is no stranger to arbitrary calculations, thus the 20 year length of a patent term is intended to provide an opportunity for the compensation of all inventors, whatever the area of technology. Similarly the 25 years exclusivity which the UPOV Convention provides for new varieties of trees and vines, takes no account of variations in R & D costs between the different varieties.

The principal ways in which plant genetic resources are translated into food and agriculture production is through plant breeding and plant patenting. Standing at the heart of a Farmers' Rights regime is the concept of the equitable benefit sharing of benefits with farmers for their contribution to innovations in plant breeding and plant patenting. 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.[55]

Article 9.2 obliges the Contracting Parties to the Plant Genetic Resources Treaty "to take measures", subject to their national legislation to protect and promote Farmers' Rights. The content of these rights is defined in the balance of that provision and embraces the protection of traditional knowledge, equitable benefit sharing and the right to participate in decision making. The Treaty leaves open the legal context within which Farmers' Rights are to be enacted.

National legislation on Farmers' Rights tends to combine one of the versions of UPOV with some of the access principles of the CBD. The African Model legislation for the Protection of the Rights of Local communities, Farmers and Breeders, and for the Regulation of Access to Biological Resources, which was adopted by the OAU, Heads of States Summit at Ouagadougou in June 1998, adopts a sui generis regime based on UPOV 1991. However, most national statutes prefer access legislation combined with UPOV 1978 (eg Andean Community's Common System on Access to Genetic Resources, 1996; Costa Rica- Biodiversity Law 1998; India- Community Intellectual Property Rights Act 1999; Kenya- Seeds and Plant Varieties Act 1975;).

7.2 World Intellectual Property Organization (WIPO)

As will be recalled from the discussion above, he first significant discussion of aspects of the international intellectual property regime, which had a bearing on food security, occurred in the discussions in the Council for TRIPS on the revision of Art.27.3(b). Following the failure of the Seattle Ministerial in November 1999, this discussion shifted to the WIPO, in the

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[55] See R. 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, 399-408.

context of agitation for the inclusion of traditional knowledge within the international intellectual property regime 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."[56] 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."[57]

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.

At the WIPO General Assembly the with 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.[58]

At the First Session of the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore ("IGC") held in Geneva from April 30 to May 3, 2001, the Member States determined the agenda of items on which work should proceed and prioritized 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."[59]

By the Fifth Session of the IGC, which met in Geneva from July 5-15, 2003, the following resources, relevant to the issue of food security, had been developed:

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56 WIPO Doc. WO/GA/26/9

57 *Ibid.*, Annex I, 10.

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

59 See WIPO Doc, WIPO/GRTKF/IC/2/3, September 10, 2001, para.1.

A consolidated survey of the protection of traditional knowledge through IP laws and an analysis of case studies conducted by WIPO in 1998 -99 on the use of IP to protect traditional knowledge.[60]

A Draft Toolkit on Intellectual Property Management[61], which identifies concerns relating to the management of IP arising in the context of documenting traditional knowledge.

A compendium of contractual practices and clauses relating to IP, access to genetic resources and benefit-sharing.[62]

A *Technical Study on Disclosure Requirements Related to Genetic Resources and Traditional Knowledge*[63] . This study reviewed salient aspects of the patent system and of legal mechanisms concerning access to genetic resources and associated TK, and surveyed the responses to a questionnaire circulated to WIPO Member States on patent disclosure requirements.

Technical proposals, submitted by the Asian group of countries on databases and registries of traditional knowledge and biological/genetic resources, which were based on the conclusions of the WIPO Asia-Pacific Regional Seminar on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore, held in Cochin, India, from November 11 to 13, 2002.[64]

The WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore will meet in Geneva from 15 to 19 March 2004. In relation to genetic resources it will consider the following four matters: (1) Draft Intellectual Property Guidelines for Access and Benefit Sharing Contracts (Doc WIPO/GRTKF/IC/6/5); (2) genetic resources and patent disclosure requirements (Doc WIPO/GRTKF/IC/6/9); (3) defensive protection measures relating to intellectual property, genetic resources and traditional knowledge (Doc WIPO/GRTKF/IC/6/8); and, the international dimension of the protection of traditional knowledge, traditional cultural expressions and genetic resources (Doc WIPO/GRTKF/IC/6/6).[65]

(1) *Draft Intellectual Property Guidelines for Access and Benefit Sharing Contracts*: These Guidelines have been produced using information in the WIPO Contracts Database. The guidelines seek to provide assistance in the negotiation of contracts for access to genetic resources and related information, including traditional knowledge, and for benefit-sharing

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60 See WIPO Doc., WIPO/GRTKF/IC/5/8 and WIPO/GRTKF/IC/5/7, which updates and consolidates the information received through the survey WIPO/GRTKF/IC/2/5 and the *questionnaires circulated to Member States.*

61 See WIPO Doc., WIPO/GRTKF/IC/5/5.

62 See WIPO Doc. WIPO/GRTKF/IC/5/9.

63 See WIPO Doc. WIPO/GRTKF/IC/5/10**.**

64 See WIPO Doc. WIPO/GRTKF/IC/4/14.

65 Draft Agenda, Doc WIPO/GRTKF/IC/6/1, 1/12/2003

arrangements.[66] At the time of writing the full text of the guidelines have not yet been released for publication by the WIPO Secretariat.

(2) *Genetic Resources and Patent Disclosure Requirements*: The Committee's Draft Technical Study on patent disclosure requirements relevant to genetic resources and traditional knowledge, which was considered in its Fifth Meeting, has been transmitted by the WIPO General Assembly to the Conference of Parties (COP) to the Convention on Biological Diversity (CBD) as a technical reference document. The study was issued to the CBD Working Group in December 2003[67] and lead to the adoption of Recommendation to the COP.[68] This Recommendation for adoption by COP at its seventh meeting (9-20 February 2004) contains the following bracketed text on modalities for addressing disclosure of information about genetic resources in patent applications:

"[*Invites* the World Intellectual Property Organization to address measures regarding the interrelation of access to genetic resources and disclosure requirements in intellectual property rights applications, while recognizing the leading role of the Convention on Biological Diversity in international biological diversity issues, in particular the intellectual property-related issues raised by a proposed international certificate of [origin/source/legal provenance], as part of the accelerated work under the renewed mandate of the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore, including:

(i) Options for model provisions on proposed disclosure requirements;
(ii) Practical options for patent application procedures with regard to the triggers of disclosure requirements;
(iii) Options for incentive measures for applicants;
(iv) Identification of the implications for the functioning of disclosure requirements in various World Intellectual Property Organization-administered treaties;]"

"[*Further invites* WIPO to prepare a report for submission to Conference of the Parties at its eighth meeting on the progress of this work, taking into account, in particular, any issues that may be identified in the Ad Hoc Open-ended Working Group on Access and Benefit-Sharing in the interim.]".[69]

(3) *Defensive Protection Measures Relating to Intellectual Property, Genetic Resources and Traditional Knowledge*: As a result of the Committee's concern with both positive and defensive forms of protection for traditional knowledge and genetic resources, the Committee will consider an update on defensive protection. The document before the Committee updates a previous comprehensive survey of this matter in Doc WIPO/GRTKF/IC/5/6. The Committee will also consider the possible scope of further cooperation to

[66] WIPO Doc WIPO/GRTKF/IC/6/INF/3, 8/12/2003
[67] Doc UNEP/CBD/COP/7/6, paragraphs 10-12 & 81.
[68] Doc UNEP/CBD/COP/7/6, paragraphs 75-85.
[69] Doc UNEP/CBD/COP/7/6, Annex, page 28.

promote the development of defensive patenting strategies. Matters to be considered include: the question of the recognition of orally disclosed traditional knowledge; measures for improving the documentation of genetic resources and traditional knowledge for use in patent procedures; and methods for improving the understanding of innovations within traditional knowledge systems for the purposes of patent search and examination. In terms of future work, the Committee will consider the following two matters: (a) "the compilation of information about the criteria that apply to the determination of relevant prior art in various jurisdictions, so that where defensive publication is made for patent purposes, it would achieve the intended objectives";[70] and (b) the preparation of "recommendations or guidelines for national patent offices concerning searches in the area of inventions linked to TK (within specific technical fields) or genetic resources, with the goal of ensuring that patent authorities with little background in traditional knowledge systems are better equipped to base decisions on a clearer understanding of the manner in which TK is maintained and developed within the traditional context".[71]

(4) *The International Dimension of the Protection of Traditional Knowledge, Traditional Cultural Expressions and Genetic Resources*: As the international dimension of these matters has now been specifically included in the Committee's mandate, it will be the emergence and development of the relevant international instruments, and the relevance of those instruments to its own work. The work of the Committee on the international dimension of genetic resources will focus on: (a) the Guidelines for IP aspects of the licensing of access to genetic resources, which is discussed in paragraph 1 above; and (b) defensive strategies to ensure intellectual property rights are not improperly granted on subject matter associated with genetic and biological resources, which is discussed in paragraph 3 above.[72]

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[70] Doc WIPO/GRTKF/IC/6/8, paragraph 23.
[71] Doc WIPO/GRTKF/IC/6/8, paragraph 24.
[72] Doc WIPO/GRTKF/IC/6/6, paragraph 28.