Commission on Intellectual Property Rights

Study Paper 3b

Access to Genetic Resources, Gene-based Inventions and Agriculture

Michael Blakeney

Director, Queen Mary Intellectual Property Research Institute
Queen Mary, University of London
M.Blakeney@qmw.ac.uk

Executive Summary

This report addresses policy options for developing countries in implementing legislation dealing with plant variety rights, farmers' rights and bioprospecting in the context of the following key issues identified by the Chairman of the Council for TRIPs at its 23 March 2001 meeting:

- 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

1. The Link Between Article 27.3(b) and Development

A number of developing countries had noted the tension between the development and technology transfer objectives of the TRIPs Agreement and the way in which the Agreement made it possible for rights owners to impose unreasonable terms for technologies. Developing country Members have urged the examination, as part of the Article 71.1 review of the TRIPs Agreement, of the impact of implementing the TRIPS Agreement on the transfer and dissemination of technology and the related trade and development prospects of developing countries.

The concerns of developing countries in this area may be accommodated by capacity building in the management of biotechnological innovation and a relaxation of the implementation time-table imposed by the TRIPs Agreement.

2. Technical Issues Relating to Patent and Plant Variety Protection Under Article 27.3(b)

Analysis of the following technical issues is suggested by the terminology of Article 27.3(b): (i) what is a patentable invention for the purposes of Article 27.3(b)? (ii) what are micro-organisms for the purposes of Article 27.2? (iiii) what are plant varieties for the purposes of Article 27.3(b)? and (iv) should there be a research exception in relation to patents over plant material?

Intellectual property law attempts to draw a distinction between inventions and discoveries. The latter are not protectable. This distinction may be made in the relevant legislation or through the decisions of IP courts. Nothing in the TRIPs Agreement obliges countries to deem the isolation of genetic materials to be inventions.

Article 27(3)(b) permits WTO Members to exclude from patent protection, plants and animals and essentially biological processes for the production of plants and animals. Members are specifically not permitted to exclude from patent protection micro-organisms and non-biological and microbiological processes. However, there is no commonly accepted definition of "micro-organism" either in science or in patent office practice. The practice of patent granting offices in developed countries suggests

that there is no perceived need for a definition. The key issue for protection being whether or not the invention meets the patent granting criteria and not its subject matter. Given these difficulties it may be more advisable for developing country member states to introduce a higher threshold for patent protection in respect of living material. Broad claims should not be permitted by patent offices and that applicants should only be able to claim the exact use of the biological material as specified in the application and no other uses.

A *sui generis* regime for the protection of plant varieties under Article 27.3(b) may provide for a dual system of protection which includes both modern as well as farmers' varieties. Given the possibility of the application of patents to plant varieties, it would appear to be significant to secure within patent laws the same research exception which exists under PVR laws.

3. Technical Issues Relating to the *Sui Generis* Protection of Plant Varieties

The principal technical issues which have been raised on the implementation of effective *sui generis* protection of plant varieties are: what is meant by "effective" and what *sui generis* options are open to Member states?

Article 27.3(b) provides no guidance on what is meant by "effective". The following options have been suggested: (i) effective through enforcement; (ii) effective to protect both modern and farmers' varieties; (iii) the rights should be protected in accordance with national objectives referred to in Articles 7 and 8 of the TRIPs Agreement and the first recital of the preamble to the WTO Agreement - on sustainable development; and (iv) the protection should be consistent with international obligations that Members have assumed, for instance under the CBD.

The sui generis options which appear of greatest interest to developing countries are those which establish their rights in relation to farmers' varieties and landraces. The significance of the contribution made by traditional agricultural knowledge to IPRs and the related questions of prior informed consent and benefit sharing, requires empirical analysis.

Landraces may be excluded from IP protection by the requirement that a new variety is distinct from "varieties of common knowledge". Similarly, material in germplasm collections, might be preserved from private exploitation through the publication of information about deposited materials, thereby placing them in the public domain. Also, the distribution of collected materials may be protected by means of material transfer agreements (MTAs) which prevent the seeking of IPRs in relation to those materials (or from essentially derived varieties).

4. Ethical Issues Relating to the Patentability of Life-forms

There is a substantial literature on the ethical implications of permitting the propertisation of the "building blocks of life". There is a questioning of the capacity of industrial property offices, NGOs and life sciences companies all of which are outside the democratic process, to make policy decisions on these matters. Researchers express the concern that biomedical and agricultural research are too important to be sterilised by the intervention of private intellectual property rights. A

related concern is that the propertisation of genetic resources has resulted in the concentration of proprietary biotechnologies in a few corporations.

5. Relationship of Article 27.3(2) to the Conservation and Sustainable Use of Genetic Material

Recommendations on the substantive content of the relationship of Article 27.3(2) to the conservation and sustainable use of genetic material is addressed below, in the context of Farmers' Rights legislation.

Procedurally, The WWF and CIEL (2001) have urged the granting of observer status for the CBD on the Council for TRIPs, to emphasisze the importance for developing countries of harmonizing the TRIPs agreement with the CBD.

6. Relationship of Article 27.3(b) With the Concepts of Traditional Knowledge and Farmers' Rights.

Farmers' Rights are enshrined in Article 9 of the Treaty on Plant Genetic Resources, as a means of recognizing "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". This recognition is recommended to be implemented through national legislation which protects traditional knowledge relevant to plant genetic resources for food and agriculture; confers a right to equitably participate in sharing benefits arising from the utilization of these resources and a right to participate in national decision making on matters related to the conservation and sustainable use of these resources. The rights of farmers have to save, use, exchange and sell farm-saved seed/propagating material is confirmed in the Article.

At least five possible legal contexts within which Farmers' Rights might be enacted: have been identified (a) biodiversity law; (b) intellectual property law; (c) traditional knowledge law; (d) human rights law; or (e) *sui generis* legislation. Of these options, *sui generis* Farmers' Rights legislation appears to be the preferred option for national legislation combining 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 is a useful precedent.

Report

1. Plants and Plant Genetic Resources and the TRIPs Agreement

Access to the plant genetic resources of a country is governed by an evolving composite of national legislation pursuant to the Convention on Biological Diversity (CBD), the TRIPs Agreement, the International Convention for the Protection of New Varieties of Plants (UPOV) and voluntary codes of international practice developed within the context of the FAO Global System for the Conservation and Utilization of Plant Genetic Resources for Food and Agriculture.

The inter-relationship between these instruments has been addressed by the Council on TRIPs purusuant to its review of Article 27.3(b), which commenced in 1999. At the 23 March 2001 meeting of the Council on TRIPs, the Chairman set out a list of key issues which had arisen in the review of Article 27.3(b)(IP/C/M/26). 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.

This report addresses each of these issues, in the context of developing country proposals to implement legislation dealing with plant variety rights, farmers' rights and bioprospecting.

2. The Link Between Article 27.3(b) and Development

A number of developing countries had noted the tension between the development and technology transfer objectives of the TRIPs Agreement and the way in which the Agreement made it possible for rights owners to impose unreasonable terms for technologies.

The objectives of the TRIPs Agreement are stated in Art. 7 in the following terms:

> The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.

Given that technology transfer to facilitate economic development is stated as the objective of the TRIPs Agreement, WTO Members are urged in a South Centre Report (Stillwell and Monagle, 2000) to "examine as part of the Article 71.1 review the impact of implementing the TRIPS Agreement on the transfer and dissemination of technology and the related trade and development prospects of developing countries", with a view to "operationalizing these provisions". For example, in relation to Art. 66.2, it is suggested that developed countries should "provide more

specific information on any existing schemes including the precise incentives, number of applying firms, and the effectiveness of these measures." To the extent that intellectual property rules do not promote technology transfer, it is suggested that "WTO Members should consider the establishment of additional mechanisms to facilitate access by developing and least-developed countries to technologies on a reasonable basis in order to fully implement the TRIPS Agreement, and to harmonize its operation with the broader objectives of the WTO Agreement."

India, noting the difficulties faced by developing countries to obtain access to foreign technology, has indicated the need to address that issue under the several provisions of the TRIPS Agreement, such as articles 7, 8, 30, 31, 40, 66.2 and 67. It has argued that "prospective technology seekers in developing countries face serious difficulties in their commercial dealings with technology holders in the developed countries" and that "the TRIPS Agreement may be reviewed to consider ways and means to operationalize the objective and principles in respect of transfer and dissemination of technology to developing countries, particularly the least developed amongst them".

The relationship between the TRIPs Agreement and development has been raised narrowly in the contexts of the implementation of the Agreement and more transcedentally in the context of human rights.

A number of developing countries have questioned what they consider to be unreasonable pressures by developed countries to impose compliance with the TRIPs Agreement. Thus the Dominican Republic and Honduras have observed that

Ever since the end of the Uruguay Round, all countries, developed and developing alike, have been racing against time to ensure due compliance at the national level with the provisions of this Agreement. However, during the transition period granted to the developing countries, we have seen selective unilateral pressures unleashed against countries that have tried to exercise their legitimate rights in full compliance with the letter and spirit of the Agreement.

Developing countries have contrasted the pressure imposed on them to implement the TRIPs Agreement with the failure of developed countries to provide incentives for the transfer of technology to, as required by Art. 66.2 and to provide technical assistance to developing countries, as required by Art.67.

A number of developing countries (eg Cuba, Dominican Republic, Egypt, Honduras) have indicated that the transitional implementation period of five years, granted under Art. 65.2 has been insufficient to undertake the complex and costly administrative tasks required under the TRIPs Agreement, such as the modernization of their administrative infrastructure (intellectual property offices and institutions, the judicial and customs system), as well as the promulgation of new intellectual property laws. They have, therefore, sought an extension of the transition period for the developing countries.

Opposed to the desire of developing countries to delay the implementation of the TRIPs Agreement are pressures from developed countries to initiate the review of the implementation of the Agreement under Art. 71.1._The European Union has

reminded negotiators that the TRIPs Agreement establishes minimum intellectual property standards "from which to seek further improvements in the protection of IPR. There should therefore be no question, in future negotiations, of lowering of standards or granting of further transitional periods" (WT/GC/W/193). Similarly Japan has declared that "We should not discuss the TRIPS Agreement with a view to reducing the current level of protection of intellectual property rights. To the contrary, the TRIPS Agreement should be improved properly in line with new technological development and social needs" (WT/GC/W/242).

The development implications of Article 27.3(b) are raised in four contexts:

7 The extensive appropriation by corporations in developed countries of intellectual property rights in genes and plant varieties, as well as in enabling technologies, raises the concern of developing countries that their research in plant genetic resources will be stultified (Correa 2001 estimates that only 6% of the 25,000 biotechnological patents granted between 1990 and 1995 were obtained in developing countries) and that such research will be concentrated in the hands of a few multinational industrial seed suppliers (see Lesser 1998b).
8 A number of notorious instances in which IPRs have been obtained by applicants from the North in relation to genetic resources obtained from the South have raised concerns that the international IP regime is being maintained in a way which encourages so-called "biopiracy", instead of benefit-sharing. (see Blakeney, 1997b; Mooney, 1998; Dutfield, 2000b).
9 The tendency of patent offices in developed countries to grant broad scope patents, over both processes and species also has the effect of annexing for enterprises in those countries, large areas of potential biotechnological invention, to the disadvantage of developing countries.
10 Similarly, the seeking of IPRs over material acquired from germplasm collections maintained by the Consultative Group on International Agricultural Research (CGIAR) in trust for the international community has also called into question the integrity of the international IP system. (See Blakeney, M. 1998)

Capacity building is required in developing countries to enable them to deal with the impacts of IPRs upon biotechnological research. Jackson (2000 at 843) proposes the establishment, in Geneva, of a Genetic Resource and International Trade Institute "to provide technical assistance training and research on genetic resources management and the rapidly changing policy environment to developing countries".

The 'biopiracy' concerns of developing countries are being addressed in the various international fora which are considering the introduction in patent and PVP regimes of a mandatory obligation, in biotechnology patent applications to identify source countries.

The granting by patent offices of over-broad patent claims is not easily susceptible of harmonized international action. To some extent, countries can give public policy directions to their patent offices, but these will be subject to judicial review.

Concerns about the extent of IPRs obtained over material acquired from germplasm collections maintained by the Consultative Group on International Agricultural Research (CGIAR), will be addressed, in the first instance, in the context of the Treaty on Plant Genetic Resources.

3. Technical Issues Relating to Patent and Plant Variety Protection Under Article 27.3(b)

Article 27.1 of the TRIPs Agreement provides that, subject to two categories of exception, "patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application". Excluded from patentability, by Art.27.2 is the exploitation of inventions "which is necessary to protect ordre public or morality, including to protect human or plant life or health or to avoid serious prejudice to the environment…." Article 27.3 permits the exclusion from patentability of :

> (b) plants and animals, other than microorganisms, and essentially biological processes for the production of plants and animals, other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective sui generis system or by any combination thereof.

In relation to genetic resources, the following technical issues are suggested by the terminology of these provisions: (i) what is a patentable invention for the purposes of Article 27.3(b)? (ii) what are micro-organisms for the purposes of Article 27.2? (iiii) what are plant varieties for the purposes of Article 27.3(b)? and (iv) should there be a research exception in relation to patents over plant material?

3.1 What is a Patentable Invention?

The modern biotechnological revolution has enabled the engineering of desirable genetic traits from useful local species. Genetic engineering has permitted the expeditious introduction of a wide range of desirable traits into plants. These include:

- pest control traits such as insect, virus and nematode resistance as well as herbicide tolerance; post-harvest traits such as delayed ripening of spoilage prone fruits;
- agronomic traits such as nitrogen fixation and utilisation, restricted branching, environmental stress tolerance,
- male and/or seed sterility for hybrid systems; and
- output traits such as plant colour and vitamin enrichment (see Lindner, 1999).

The production of transgenic plants has become possible through the development of a number of enabling and transformation technologies. These technologies, together with the introduction of beneficial plant traits, have become the subject of intellectual property protection, as a consequence of the favourable decisions of courts in the USA and Europe (see Blakeney, 2001a)

Intellectual property law attempts to draw a distinction between inventions and discoveries. The latter are not protectable. This distinction may be made in the relevant legislation eg the Nicaraguan Plant Variety Protection Law of 1999 provides that discoveries may not be protected. Additionally, IP courts distinguish between the discovery of non-patentable material which exists in nature and patentable inventions. The general approach which patent offices have taken, following the US Supreme Court decision in *Diamond* v *Chakrabarty* (447 US 303 (1980)) is that gene-sequences are inventions when they have been isolated and purified (see Doll, 1998). In Europe the Directive on the Legal Protection of Biotechnological Inventions (98/44/EC of 6 July, 1998), specifically provides in Article 3.2 that "Biological material which is isolated from its natural environment or produced by means of a technical process may be the subject of an invention even if it previously occurred in nature".

Similarly transgenic plants and following the *Harvard/Onco-mouse* determination (*Official Journal* European Patent Office 1989, 451; 1990, 476; 1992, 558) transgenic animals are considered to be inventions.

Patents have been granted for plant varieties in Australia and the USA (see Correa 2001). Processes for the production of varieties of transgenic plants are patentable, even in Europe, which denies patents to single varieties. (*Novartis/Transgenic Plant* discussed in Llewelyn, 1999).

Although patent offices in developed countries have permitted the patenting also of partial DNA sequences and Expressed Sequence Tags (ESTs), ASSINSEL has submitted that where these are not associated with an expressed characteristic, they should not be patented and that crop traits, as such, should not be patented. (ASSINSEL 1999).

Of course, it is equally open to a court or a legislature to rule or provide that genetic material is not patentable, even in its isolated or purified form, because it is a mere discovery. Indeed, nothing in the TRIPs Agreement obliges countries to deem the isolation of genetic materials to be inventions. A number of developing countries exclude the patentability of genetic materials (Mexico), or of materials existing in nature (Argentina, Brazil and the Andean Group Decision 344).

3.2 What are Micro-organisms for the Purposes of Art.27.3(b)?

Article 27(3)(b) permits WTO Members to exclude from patent protection, plants and animals and essentially biological processes for the production of plants and animals. Members are specifically not permitted to exclude from patent protection micro-organisms and non-biological and microbiological processes. The language used in Article 27(3)(b) implies that a clear distinction can be made between plants and animals on the one hand and micro-organisms on the other. However, there is no commonly accepted definition of "micro-organism" either in science or in patent office practice. The lack of any definition permits great variations between members in restricting this exclusion from patentability. For example, from the patent activity taking place in the United States, Europe and Japan, it has been observed that a very

flexible interpretation is given to the concept of patentable subject matter, where the emphasis is on inclusion not exclusion (Adcock and Llewelyn, 2000).

A South Centre report on *Technical Issues on Protecting Plant Varieties by Effective Sui Generis Systems* (Mangeni ,2000, para. 24), urges the adoption, even of a narrow scientific definition of micro-organism "viruses, algae, bacteria and protozoa" to give some certainty to the exception.

The practice of patent granting offices in developed countries suggests that there is no perceived need for a definition. The key issue for protection being whether or not the invention meets the patent granting criteria and not its subject matter. One of the reasons for reluctance to use a definition, provided by the European Patent Office (EPO) was that "it does not seem expedient to introduce such a definition as the rapid evolution in the field of microbiology would necessitate its frequent updating" (quoted in Adcock and Llewelyn, 2000).

In scientific practice the term "micro-organism" is ill-defined, because the scientific classification is continually evolving. In patent office practice, the only debate of any kind has taken place in Europe in the context of what constitutes a plant, which is patentable, and a plant variety, which is not. The result of this has been agreement within patent granting offices that excluded material is that which is protectable by a plant variety right as determined by the UPOV Convention, anything falling outside the scope of UPOV being protectable by a patent (Lewelyn, 2000). The result of this is that patent protection is available for groupings of plants which encompass more that one variety provided the patentee has not claimed a plant variety as such. Anything, therefore, which does not take the form of a patent variety as such is patentable. It has not been regarded as necessary to provide any further definitions. The patent laws of developed countries are predicated on a presumption of patentability and the granting criteria are given a broad interpretation. Any exclusions are, therefore, given a restriction application. Thus where a country has adopted specific categories of excluded material, these exclusions are likely to be the subject of rigorous scrutiny particularly where the categories could be said to go beyond that which is permitted under the TRIPs Agreement (Adcock and Llewelyn, 2000).

Given the difficulties inherent in attempting a definition of micro-organism, it may be more advisable for member states to introduce a higher threshold for patent protection in respect of living material. For example, Adcock and Llewelyn (2000) suggest that an invention involving biological material may not be regarded as novel: (a) if the information is already in the public domain; and/or b) the invention merely replicates biological material, or the function of biological material, which already occurs naturally. Mangeni (2000) suggests the exclusion from novelty of any information available to the public, whether in writing "or though use including use by local and indigenous communities and through the deposit of information with deposit institutions, such as genebanks".

An invention involving biological material will be regarded as lacking an inventive step if it: (a) merely identifies the biological material; and/or (b) merely identifies the natural function of the biological material. An invention will demonstrate an inventive step if it takes the form of a significant technical application of an identified function of the biological material. This technical application must go beyond a mere simple replication of the natural function of the biological material,

and the technical application must represent a significant technical advance on the prior art.

An invention involving biological material will be regarded as being capable of industrial application if it can be shown that it is capable of being used in a manner which provides a demonstrable public benefit. Public benefit means that the invention must be capable of being used in a manner conducive to public health and to social, environmental and economic welfare.

Adcock and Llewelyn (2000) also suggest that broad claims should not be permitted by patent offices and that applicants should only be able to claim the exact use of the biological material as specified in the application and no other uses.

The current low thresholds for protection applied by the US and the European patent offices means that the courts are becoming the arbiters of patentability, as the revocation of the Neem and Turmeric patents demonstrate. The argument for raising the threshold for protection can be justified on the basis that it will result in greater predictability and certainty for the bioscience industry, ensuring that those inventions which deserve protection are protected and that this protection is less likely to be subsequently challenged in court (Adcock and Llewelyn). The re-opening of the Neem and Turmeric patents are cited as examples of courts being forced to reconsider the liberality of patent offices (see Das, 2000; Prakash, 2000). On the other hand, they may be considered to be examples of the necessity for patent offices to have access to data on traditional knowledge as part of the state of the art.

3.3 What is a Plant Variety for the Purposes of Article 27.3(b)?

As noted above, a crucial issue in the establishment of a *sui generis* regime would be the definition of the protected subject matter. Article 27.3b of the TRIPs Agreement requires the protection of "plant varieties", but does not provide (as in the case of inventions) a definition thereof. Therefore, national laws have ample room to determine what is to be deemed a plant "variety" for the purposes of protection. There have been lengthy discussions on the concept of "plant variety", particularly in the framework of UPOV. The scientific notion does not necessarily coincide with the legal concept. The law may require certain characteristics for a *protected* variety that may not be essential for a scientific definition.

Correa (2000b at 30-32) has suggested that a *sui generis* regime may provide for a dual system of protection which includes both "modern" as well as farmers' varieties. Modern varieties would be protected under a UPOV-like legislation, requiring novelty, distinctness, uniformity and stability. For other cases (farmers' varieties) the requirements may be less stringent and be limited, for instance, to sufficient identification and distinctness. This distinction would take account of the more variable nature of farmers' varieties. Since the creation of the latter variety is generally a collective endeavour, the rights would be granted to the community that has developed and used the variety. In the case of farmers' varieties, national legislation may recognize a "remuneration right", that is, an entitlement to receive compensation in all cases of use of a protected variety for propagating purposes outside the respective farming community or communities. This formulation would amount, in practice, to an open licensing system under which any interested party may utilize the

protected variety for planting or multiplication, against a payment in favour of the titleholders.

Another possibility for protecting farmers' varieties, suggested by Correa (2000b at 32-33) would be through a regime that aims to prevent the misappropriation of such varieties. National legislation would provide that intellectual property rights could not be obtained with respect to farmers' varieties (or derivatives therefrom). In the case of infringement of this rule, the conferred title should be declared void. Given the collective nature of these rights and the lack of legal personality for farmers communities, Correa (222b at 32) suggests the establishment of an "ombdusman" empowered with the right to act on behalf of the communities so as to enforce their rights.

The features of the misappropriation regime, suggested by Correa (2000b at 32-33) are:

- it would recognize the informal, collective and cumulative systems of innovation of local and indigenous communities and farmers;
- no novelty, inventiveness or secrecy would be required;
- there would be no arbitrary time limit for protection;
- the conferred rights would be "non-monopolistic" and would not hinder the non-commercial use and exchange of germplasm within and among communities;
- no registration, and therefore, administrative machinery, would be necessary;
- it would not oblige farmers or communities' members to keep secrecy or change their traditional practices;
- since no monopolies would be recognized, possession of the same knowledge by different communities would be perfectly legitimate;
- the rights against infringers would arise when a variety has been acquired in a manner contrary to certain rules, such as national access legislation or other accepted practices on the collection of germplasm.

3.4 Research Exception

Given the possibility of the application of patents to plant varieties, it would appear to be significant to secure within patent laws the same research exception which exists under PVR laws. Under European and US patent case law, the courts have permitted experimentation for the purposes of invention outside the scope of the patent. This judge-made exception is subject to the vagaries of judicial interpretation. In Japan, the exception is created by statute (Patent Law, s.69(1)).

Correa (2001) refers to the recommendation by "experts in the United States of an explicit research exemption for patents on plants and cites Barton (1993b at 9) for the suggestion that all biological materials required for IPR protection become 'part of the national germplasm system'".

4. Technical Issues Relating to the *Sui Generis* Protection of Plant Varieties.

The principal technical issues which have been raised on the implementation of effective *sui generis* protection of plant varieties are: (a) what is meant by "effective"? and (b) what *sui generis* options are open to Member states?

4.1 "Effective" *Sui Generis* System

Article 27.3(b) provides no guidance on what is meant by "effective", the debate in the TRIPs Council having focused upon which sui generis systems satisfy the obligation, One interpretation is that effective refers to the enforceability of the PVP rights granted by the relevant legislation (Blakeney, 1996). Mangeni (2000) asserts that if the debate shifted to the meaning and implication of "effective", the following would be among the conclusions reached:

- the *sui generis* system should be effective to *protect plant varieties* as such (including varieties developed by local communities and national/public research institutes);
- the rights of plant breeders should be protected as an international obligation as and when assumed by Members;
- the rights to be protected should be those set out in the obligations Members have assumed (for instance under the Agreement on TRIPs and equally the CBD;
- the rights should be protected in accordance with national objectives referred to in article 7 and the principles in article 8 (Agreement on TRIPs) as apply in the country should be protected within the overall framework of the CBD and the first recital of the preamble to the WTO Agreement - on sustainable development, and
- the protection should be consistent with international obligations that Members have assumed, for instance under the CBD.

4.2 *Sui Generis* Options

The UPOV system is urged as the principal workable example of a *sui generis* plant variety protection system. It is interesting to note that the drafters of the TRIPs Agreement, who felt free to import into the agreement, provisions from other named international instruments, such as the Paris, Berne and Rome Conventions and the Washington Treaty on Integrated Circuits, in the area of plant varieties desisted from importing the UPOV Convention.

The UPOV Convention has been revised on several occasions. The two versions which are the subject of most attention are the Acts of 1978 and 1991. The principal differences between these two versions are set out in the table below.

Key provisions	**UPOV 1978**	**UPOV 1991**
Breeders' exemption	included	Included
Principle of essential derivation	not included	Included
Scope of protection	only traded material	all materials - harvested product - end product (optional)

No of species to be protected	minimal 24	All
Duraton of protection	15-18 years	20-25 years
Double protection (patents and PVP)	not possible	Permitted

A number of developing countries have issued papers on options for national plant variety legislation. These are conveniently summarized by GRAIN 2000, as follows:

Developing countries' proposals for the review of article 27.3(b) of the TRIPs Agreement

Countries/ Organizations	**Patenting (life forms & biological processes)**	***Sui generis* (plant varieties)**
Kenya (WT/GC/W/23 of 5 July 1999)	Need five-year extension of transition period Harmonize TRIPs with CBD	Need five-year extension of transition period Increase scope of 27.3(b) to include protection of indigenous knowledge and farmers' rights Harmonize TRIPs with CBD
Venezuela (WT/GC/W/282 of 6 August 1999)	In 2000, introduce mandatory system of IPR protection for traditional knowledge of indigenous and local communities, based on the need to recognize collective rights	
African Group (WT/GC/W/302 of 6 August 1999)	Review should be extended + additional five year transition hereafter Review should clarify that plants, animals, microorganisms, their parts and natural processes cannot be patented	Review should be extended + additional five year transition after that *Sui generis* laws should allow for protection of community rights, continuation of farmers' practices and prevention of anti-competitive practices which threaten food sovereignty Harmonize TRIPs with CBD and IU of FAO
LDC Group (WT/GC/W/251 of 13 July 1999)	There should be a formal clarification that naturally occurring plants and animals, as well as their parts (gene sequences), plus essentially biological	*Sui generis* provisions must be flexible enough to suit each country's seed supply system Need for extended transition period

	processes, are not patentable. Incorporate provision that patents must not be granted without prior informed consent of country of origin Patents inconsistent with CBD Art 15 (access) should not be granted Need for extended transition period	
Jamaica, Sri Lanka, Tanzania, Uganda, Zambia (www.foe.org/international/wto/gov 2 September 1999)	No patenting of plants without prior informed consent of government and communities in country of origin	
SAARC (South Asia Association for Regional Cooperation (SAARC), WT/L/326, 22 October 1999)	There is a need to prevent piracy of traditional knowledge built around bio-diversity and to seek the harmonization of the TRIPs Agreement with the U.N. Convention on Biological Diversity so as to ensure appropriate returns to traditional communities.	
SADC (Southern Africa Development Cooperation WT/L/317, 1 October 1999)	The transitional period for implementation of 27.3(b) should be extended and the 2000 review should be delayed. The review of 27.3(b) should harmonize TRIPs with CBD. The exclusion of essentially biological processes from patentability should extend to microbiological processes.	The transitional period for implementation of 27.3(b) should be extended and the 2000 review should be delayed. The review of 27.3(b) should retain the *sui generis* option.
Group of 77 (WT/MIN(99)/3, 2 November 1999)	Future negotiations must make operational the provisions relating to the transfer of technology, to the mutual advantage of producers and users of technological knowledge and seek mechanisms for a balanced protection of biological resources and disciplines to protect traditional knowledge	
Bolivia, Colombia, Ecuador, Nicaragua, and Perú	The Seattle Ministerial Conference should adopt a mandate to: (a) carry out studies in order to make	

(WT/GC/W/362,12 October 1999)	recommendations on the most appropriate means of recognizing and protecting traditional knowledge (TK) as the subject matter of IPR; (b) initiate negotiations with a view to establishing a multilateral legal framework that will grant effective protection to the expressions and manifestations of TK; (c) complete the legal framework envisaged in paragraph (b) above in time for it to be included as part of the results of the new round of trade negotiations.

At 6 August 2001, some 49 states had acceded to the UPOV Convention (see Annex II). Of these, 29 states had acceded to UPOV 1978, 19 to UPOV 1991 and 2 states to UPOV 1961/1972. Mangeni (2000) states that the preference of developing countries is for UPOV 78 because of its reference to the right of farmers to save, replant and share seeds and because of the breeder's exemption to research, experiment and breed around the protected variety without undue claims from the breeder of the protected variety. He also asserts that it provides "better protection for biodiversity, which developing countries consider beneficial for social justice in catering to local communities or the rural population and farmers, and for being supportive of domestic policies like promoting innovation and attaining food security".

Ghijsen (1998) suggests that different Plant Variety Protection (PVP) issues arise in relation to three distinct categories of plant: (a) open pollinated food crops; (b) inbred lines and horticultural crops; and (c) medicinal plants.

In relation to open pollinated food crops such as cereals and tubers, seed saving is important for farmers in developing countries.

Landraces are excluded from protection by the requirement that a new variety is distinct from "varieties of common knowledge". Similarly, material in germplasm collections, might be preserved from private exploitation through the publication of information about deposited materials,thereby placing them in the public domain. More importantly, the distribution of collected materials may be protected by means of material transfer agreements (MTAs) which prevent the seeking of IPRs in relation to those materials (or from essentially derived varieties).

For inbred lines and horticultural crops, such as ornamentals, fruits, vegetables and plantation crops, seed saving is not generally an attractive option for farmers.

In relation to medicinal plants, Ghijsen (1998) suggests the requirement of a certificate of novelty as a precondition for PVP. This would assure that important plants remain in the public domain. Another option, suggested by the PVP law of Ecuador, is that PVP cannot be obtained for wild species which have not been planted or improved by human intervention.

Leskien and Flitner (1997) have suggested a PVP seal, which allows the holder of the right to use the seal on seed packages of the protected variety. After the seed has been purchased the PVP right will be exhausted and any further transactions with the seed

will be permissible. This suggestion has been criticised as an encouragement to piracy (Louwaars, 1998), although it should be noted that the exhaustion principle applies to trademarks.

The WWF and CIEL (2001) encourage the Secretariat of the CBD to compile further case studies and empirical evidence on the relationship between IPRs and TRIPs, particularly focussing on the relationship between IPRs and access and benefit sharing and the impact of IPRs on technology transfer. They urge that "IPRs will need to be evaluated to ensure that they do not 'run counter' to the objectives of the CBD.

The South Centre report (Mangeni, 2000) recommendations include:

1. the existing provision in article 27.3(b) for the protection of plant varieties by sui generis systems should be kept.

2. the provision should be construed and amended to be in conformity with other international obligations on the matter of protecting plant varieties, including those under the Convention on Biological Diversity

3. the rights of breeders include research and experimentation, and innovation for purposes of seeking protection of consequent varieties, without compensatory claims

4. local farmers in developing countries have the right to save, share, sell, and replant seed, without compensatory claims from plant breeders

5. intellectual property rights that contravene the Convention on Biological Diversity and article 27.3(b) as modified (to provide that plant varieties are to be protected by sui generis systems and that any intellectual property rights must be subject to the Convention on Biological Diversity and the FAO International Undertaking on Plant Genetic Resources) are not to be granted and are to be cancelled by the offices on their own motion or on petition

6. novelty is to mean universal novelty, in particular material for which an intellectual property right is sought is not novel if based on or it contains information available to the public through writing or use, including use by communities, or through deposit in deposit institutions.

5. Ethical Issues Relating to the Patentability of Life-forms

There is a substantial literature on the ethical implications of permitting the propertisation of the "building blocks of life" (Eg see Suzuki and Knudson, 1989). A number of religions consider human intervention in relation to living material to "violate" the divine creation, or at least to "reduce the value of life and nature to the merely economic" (Bruce and Bruce, 1998 at 231). Furthermore, the decisions in relation to these important matters are taken by entities, such as industrial property offices, which are outside democratic control. Similarly the proponents on either side of the patenting life debate, whether NGOs or life sciences companies are also outside the democratic process. This "democratic deficit" counsels at least education of

politicians, the public and the media in all aspects of the commodification of life. (Bruce and Bruce, 1998 at 270-271, cited by Tansey, 1999 at 19).

Researchers express the concern that biomedical and agricultural research are too important to be sterilised by the intervention of private intellectual property rights. The decision of the National Institute of Health to file patent applications for gene sequences was described as "sheer lunacy" by James Watson, the first Director of the Human Genome Programme, and cited as one of the reasons for his resignation (see McKeough, 1997).

A related concern is that the propertisation of genetic resources has resulted in the concentration of proprietary biotechnologies in a few corporations (Eg see Wells, 1994; Lesser, 1998b). In addition to the possible adverse impacts this market concentration might have upon the vigour of competition, the market dominance of these private corporations also has an important influence upon the sort of biotechnological research which is undertaken. For example, to what extent will the dominance of private corporations in biomedical and agricultural research direct that research towards Northern concerns such as away from Southern health problems (see Wattal, 2000) and Southern food priorities (see Alston, Pardy and Roseboom, 1998). Will the owners of IPRs in key enabling technologies make them available to public research institutions on affordable terms ? (see Leisinger, 1999).

The concentration of proprietary technologies in the hands of a relatively small group of Northern life-sciences companies, has been exacerbated by the grant, by patent offices of over-broad patent claims, resulting in what Heller and Eisenberg (1998) have described as the "biomedical anticommons tragedy". This problem, as is mentioned above, can only to a limited extent be dealt with by policy directions to patent offices, as ultimately the interpretation of patent claims is a matter for the courts.

Article.27.2 of the TRIPs Agreement, it will be recalled, permits Members to disallow the exploitation of inventions "which is necessary to protect ordre public or morality, including to protect human or plant life or health or to avoid serious prejudice to the environment….". Member states would have to show that the commercial exploitation of the specific invention, would be contrary to *ordre public* or morality. In light of the interpretation and application of the equivalent provision within the European Patent Convention, and recently reinforced in the EU Directive on the Legal Protection of Biotechnological Inventions, it is unlikely that this exception would permit a general exclusion of living material from patentability. It is also questionable whether patent offices are the proper bodies to adjudicate the application of moral and ethical issues to the patent system (see Ford, 1997; Warren, 1998; Walter, 1998).

In any event, the patent offices have abstained from exercising moral judgements in this area. Thus for example in *Greenpeace v Plant Genetic Systems NV* (OJ EPO 8/1995 545), in an opposition to an application for a patent directed to transgenic plants engineered to be resistant to the herbicide Basta, Greenpeace argued that it was immoral and therefore in breach of Article 53(a) of the European Patent Convention, to "own" plants which were the common heritage of humankind. The Appeal Board

of the EPO, sustained the Examination Division's view that it was not the proper forum for discussing the advantages and disadvantages of genetic engineering. Similarly in *Novartis/Transgenic Plants* (Decision G0001 of 20 December 1999) the Extended Board of Appeal of the EPO, considered the debate over genetic engineering to be too controversial for it to sustain Greenpeace's opposition to the patent. The Extended Board of Appeal noted that the European Patent Directive on Biotechnology was an indication that the European Parliament considered there to be some benefit in genetic engineering.

On the other hand, the European Biotechnology Directive is an example of a legislature giving directions to its patent office on matters to be considered in evaluating the morality of an invention (see Leskien 1997). The Directive excludes from patentability:

- the human body in its various stages;
- processes for cloning human beings;
- processes for modifying the genetic identity of human beings in the germ line;
- the use of human embryos for industrial or commercial purposes;
- processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial benefit to humans or animals, and also animals resulting from such processes.

Arguably, a national legislature could take the position that equitable benefit sharing, prior consent and even the farmer's seed saving privilege could be matters of ethical concern, on which directions could be provided to the patent office.

6. Relationship of Article 27.3(2) to the Conservation and Sustainable Use of Genetic Material

The TRIPs Agreement is primarily concerned with Member nations' obligations to establish a legal infrastructure to permit the privatisation of intellectual property rights. Article 27.3(b) permits the extension of those private rights to genetic resources. The TRIPs Agreement is seen by some to be in tension with the Convention on Biological Diversity (CBD), which is concerned with conserving the "global genetic commons" for humankind (eg Buck, 1998, Lawson and Pickering, 2001, Meyers, 2000). The Conference of the Parties (COP) to the CBD has reported that the value and benefit of genetic materials in the global biosphere may be realised and shared through IPRs (CBD, 1996a). The COP Secretariat has also noted the importance in the relationship between trade and biological diversity of the interrelationship between the TRIPs Agreement and the CBD (CBD, 1996b). The COP Panel of Experts on Access and Benefit Sharing concluded that IPRs were a significant influence upon benefit-sharing (CBD, 1999), but consensus has not been achieved within the COP on whether this influence has been positive or negative.

A similar lack of consensus has characterised the examination of the benefit sharing aspects of the CBD, within the context of the TRIPs Agreement, the WTO Committee on Trade and the Environment (See WTO, 1999).

A critical factor, bearing upon benefit sharing, which does not appear to have been considered either by the COP, or the Trade and Environment Committee, is the effect of patentability standards. Permitting broad patent sequence claims will restrict the availability of genetic resources, act as a disincentive to innovation, delaying key research and contributing to the concentration of ownership over key genetic resources (see, Barton, 1993; Lawson and Pickering, 2001). The TRIPs Agreement does not address the practices of patent offices in the breadth of the claims which they will accept. If the benefit-sharing obligation of the CBD was imported into Article 27.3(b), this may act as a constraint in permitting over-broad claims.

Recommendations on the substantive content of the relationship of Article 27.3(2) to the conservation and sustainable use of genetic material is addressed in section 7.2.1 below, in the context of Farmers' Rights legislation.

Procedurally, The WWF and CIEL (2001) have urged the granting of observer status for the CBD on the Council for TRIPs, to emphasisze the importance for developing countries of harmonizing the TRIPs agreement with the CBD.

7. Relationship of Article 27.3(b) With the Concepts of Traditional Knowledge and Farmers' Rights.

The concept of Farmer's Rights was formulated in 1989, in the context of the FAO International Undertaking on Plant Genetic Resources (IUPGR). The IUPGR, adopted by the FAO in 1983 and subscribed to by most FAO members, excluding the USA., establishes protocols for: exploration and collection of genetic resources (Art.3), for conservation *in situ* and *ex situ* (Art.4), for the availability of plant genetic resources (Art.5), for international cooperation in conservation, exchange and plant breeding (Art.6), for international coordination of genebank collections and information systems (Art.7) and for funding (Art.8).

The IUPGR was originally predicated on the principle that plant genetic resources should be freely exchanged as a "heritage of mankind" and should be preserved through international conservation efforts. In subsequent years the principle of free exchange was gradually narrowed. In November 1989 the 25th Session of the FAO Conference adopted two resolutions providing an "agreed interpretation" that plant breeders' rights were not incompatible with the IUPGR. The acknowledgment of plant variety rights obviously benefitted enterprises in those countries, typically in the North, which were engaged in commercial seed production. In exchange for this concession, developing countries won endorsement of the concept of "Farmers' Rights".

Farmers' Rights were thus defined in a Resolution of the 25th session of the FAO Conference (11-19 Nov. 1989) as:

> …rights arising from the past, present and future contribution of farmers in conserving, improving and making available plant genetic resources, particularly those in centres of origin/diversity. These rights are vested in the International Community, as trustee for present and future generations of farmers, for the purpose

of ensuring full benefits to farmers, and supporting the continuation of their contributions.

Farmers' rights were intended to promote a more equitable relation between the providers and users of germplasm by creating a basis for farmers to share in the benefits derived from the germplasm which they had developed and conserved over time. An International Fund for Plant Genetic Resources was proposed in a Resolution of 1991 as a means of implementing Farmers' Rights. This Fund will support plant genetic conservation and utilization programmes, particularly in the developing countries.

Farmers' Rights are conceived of as a "retrospective equity," (Brush, 1996) primarily as the recognition of the moral obligation, rather than an economic incentive.

Between 1994 and 2001 the FAO's Commission on Genetic Food Resources for Agriculture (CGFRA) considered a number of Negotiating Texts of the International Undertaking, with a view to its adoption as a binding legal obligation, by members of the FAO. At its Sixth Extraordinary Session in June 2001 the members of CGRFA agreed the following article (FAO, 2001):

> Article 9 – Farmers' Rights
>
> 9.1 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.
> 9.2 The Contracting Parties agree that the responsibility for realizing Farmers' Rights, as they relate to Plant Genetic Resources for Food and Agriculture, rests with national governments. In accordance with their needs and priorities, each Contracting Party should, as appropriate, and subject to its national legislation, take measures to protect and promote Farmers' Rights, including:
> (a) protection of traditional knowledge relevant to plant genetic resources for food and agriculture;
> (b) the right to equitably participate in sharing benefits arising from the utilization of plant genetic resources for food and agriculture;
> (c) the right to participate in making decisions, at the national level, on matters related to the conservation and sustainable use of plant genetic resources for food and agriculture.
> 9.3 Nothing in this Article shall be interpreted to limit any rights that farmers have to save, use, exchange and sell farm-saved seed/propagating material, subject to national law and as appropriate.

This paper will analyse the salient features of the concept of Farmers' Rights as enunciated in Article 9 of the International Undertaking.

7.1 Justification for Farmers' Rights

7.1.1 Introduction

The justification for Farmers' Rights, which is advanced in the text of Art. 9.1 is the declaration by the Contracting Parties that they "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." This "recognition" in effect operates as a preamble to the operative portion of the Article contained in 9.2.

Since the text of Art.9 is to be submitted for adoption by FAO members at the 31st session of the FAO Conference in November 2001, it is useful to examine the claims made in Art.9.1 of the contribution made by local and indigenous communities and farmers of all regions for the conservation and development of plant genetic resources.

7.1.2 Conservation of Plant Genetic Resources

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. The extent of these contributions is explored in the nest section of the paper. As a means of remunerating these groups for their past contributions to the development of plant genetic resources for food and agriculture production, there can be little argument, except about the quantum and distribution of this remuneration.

A more critical question is whether a Farmers' Rights regime will encourage these groups to continue to perform this conservation function. A similar debate in Europe concerns how farmers can be encouraged to preserve the less agriculturally efficient traditional rural landscape with a view to catering to tourism. A Farmers' Rights regime, predicates that farmers in the "centres of origin and crop diversity" will continue to use landraces and traditional varieties, whatever their yields, in preference to the modern high yielding varieties, which are available in the market.

Studies of the evolution of seed supply systems identify a transition from informal seed-saving and bartering in developing countries, through a transition to the private production of seeds by private companies (Louwaars and Marrewijk, 1996). Facilitating this transition is the contribution made by public international and national agricultural research institutes. This transition may be regarded as part of the development process. Probably the most that can be expected from a Farmers' Rights system is the removal of impediments to this transition, such as those which may be presented by an intellectual property system. Thus for example, Plant Variety Rights systems ought not derogate from the right of farmers to save and exchange seed (Crucible Group II, 2000 at p.99).

It has also been pointed out that traditional farmers and indigenous communities are one category of actors in a complex of relationships between them and seed collectors, curators, research institutions, plant breeders, seed companies and

commercial farmers (ten Kate, K. and S.Laird. 1999, at p.132). The quantification of the commercial value contributed by each of these categories of actors to the development and exploitation of new plant varieties and of new agricultural patents is difficult. In the case of traditional farmers and indigenous communities, their contribution of plant genetic resources is invariably made on a non-commercial basis. Additionally, their unremunerated contribution stretches back over many decades.

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.

7.1.3 Development of Plant Genetic Resources

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.

7.1.3.1 Plant breeding

The economic value of biological diversity conserved by traditional farmers for agriculture is difficult to quantify (See Brush, 1994) 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" (Wright, 1998 at p.228). 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.

The principal germplasm collection, derived from the contribution of farmers and traditional communities, is that maintained by the Consultative Group on International Agricultural Research (CGIAR). 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 16 agricultural research centres research centres, each focussing on crops and materials of interest to developing countries. These centres are: Centro Internacional de Mejoramiento de Maiz y Trigo (CIMMYT), 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).

An indirect illustration of the value of these germplasm collections to plant breeders is the way in which third parties have sought intellectual property rights in relation to materials obtained from some CGIAR Centres. Among the most notorious of these incidents was an attempt in 1998 by a number of Australian agricultural research institutes to obtain plant variety protection in relation to a peavine and a lentil which had been bred from genetic stock obtained from the International Centre for Agricultural Research in the Dry Areas (ICARDA) and 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) (See Blakeney, 1998). The *New Scientist* castigated this as an attempt to obtain "property rights on chickpeas grown by subsistence farmers in India and Iran" (*New Scientist*, 1998). To prevent a recurrence of this incident, the operating regulations of the Australian Plant Breeders Rights Office were amended to oblige applicants for Plant Breeders' rights 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.

A second incident concerned the grant by the USPTO, 0n April 13, 1999, of a plant patent by the US Patent and Trademarks Office in relation to 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” (US Patent 5,894,079). On May 28, 1999, the applicant also obtained a U.S. Plant Variety Protection Certificate on the bean variety. On 20 December 2000 CIAT (The International Center for Tropical Agriculture) filed a formal request for re-examination of the US patent concerning the yellow bean, which was alleged to be the Mexican Enola bean (RAFI, 2001). 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. Although, there was no evidence that the patent owner had obtained his beans from CIAT's gene bank, the patent challenge noted that CIAT maintained some 260 bean samples with yellow seeds, and 6 of the accessions were 'substantially identical' to claims made in the patent. 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.

Another controversy involving CIAT concerned the grant by the USPTO on 21 March 2000 to a US applicant for a patent relating to a “bean-nut popping bean” apparently derived from crosses involving at least 33 Andean Nuna bean varieties from Peru, Bolivia, Ecuador, and Colombia (US Patent No. 6,040,503; Patent Cooperation Treaty Patent no.WO99/11115) Nine of these varieties were held in CIAT's international bean collection as designated in-trust accessions, all being farmers’ varieties collected in Peru. The patent is currently being challenged

Finally, in April 2000, the curator of the germplasm collection maintained by the International Potato Center (CIP), questioned the distribution, by CIP, of five traditional Peruvian varieties of Yacon to the Peruvian Ministry of Agriculture, which

passed them to researchers in Japan. The curator expressed concern that, apparently because of plant breeders' rights, the Japanese researchers were not prepared to send germplasm of a Yacon variety, "Sarada-Otome", developed by Japanese researchers to be tested in Peruvian farmers' fields (See Huaman, 2001). He questioned the equity of denying to a source country, new derivatives of deposited germplasm. CIP's Genetic Resources Policy Committee (GRPC) subsequently exonerated CIP from any culpability in this transaction (See Zandstra, 2001).

This incident, as well as the other episodes mentioned above raises a question which has not yet been addressed by the CGIAR or the FAO, namely, is the question of the rights, if any, of the farmers, indigenous and traditional communities in relation to plant varieties commercialised from germplasm collected from them by the various CGIAR institutes. Plant Breeders' rights is one way of dealing with an aspect of this exploitation.

7.1.3.2 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 (see McNeely, 2001) As with plant breeding, the germplasm collections of the CGIAR Centres have constituted a useful source of genetic material. A study by the World Intellectual Property Organization and the United Nations Environment Programme, of case studies of the utilization of traditional knowledge in biotechnological patenting, refers to a patent granted on 12 January 1999, by the USPTO to the Regents of the University of California, arising out of material derived from germplasm developed by the International Rice Research Institute (IRRI) (WIPO, 2001, at 13-24).

In this particular case, a strain of wild rice, *Oryza longistaminata*, which was collected by itinerant poor farmers in Mali, had been identified as being resistant to bacterial blight, a disease which particularly afflicts rice. 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 from the University of California at Davis, who was working at IRRI, was permitted with co-workers at Cornell University to map, sequence and clone the Xa21 gene (Ronald. 1998). The molecular mapping process was facilitated by the construction of a BAC library utilising a biological tool provided by IRRI.

On 7 June 1995 the Regents of the University of California, without the knowledge of IRRI, had filed a patent application for "Nucleic acids, from *Oryza sativa*, which encode leucine-rich repeat polypeptides and enhance *Xanthomonas* resistance in plants. The patent was granted by the USPTO on 12 January 1999. This patent generated some controversy in CGIAR circles because it was perceived to compromise IRRI's research efforts and those of its clients in the rice-producing regions of Asia (see Blakeney, 2000b). Bacterial blight is not a particular problem for US rice producers and a primary effect of the patent was to prevent the export of bacterial blight resistant rice, utilising the patent to the USA. This patent also raised the question of equitable compensation, at least for the itinerant poor farmers of Mali who had conserved *O. longistaminata*. The UC Davis dealt with the issue of

compensation by establishing, at the suggestion of John Barton, a Genetic Resources Recognition Fund (GRRF) as a mechanism "to provide fellowship assistance to researchers from developing countries", with priority for students from germplasm source countries. (Ronald, 1998 at 20N). 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." (P. Ronald, quoted in WIPO, 2001, at 13).

UC Davis also agreed to allow non-commercial researchers access to the gene, provided they did not develop commercial products based on that gene. The University also agreed that IRRI would have full rights to develop new rice varieties incorporating cloned Xa21 and distribute this material as well as the clone to developing countries (ten Kate and Collis, 1999). No provision was made for either IRRI, or the source community in Mali to benefit from the exploitation of the patent in relation to crops, other than rice.

7.1.3.3 Plant Variety Rights and Patenting

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.

To avoid the confusion of the double protection of PVRs under both patent and PVR laws, the patent laws of a number countries, implementing UPOV 1961, exclude the protection of plant varieties. For example, Article 53b of the European Patent Convention excludes patents for "plant and animal varieties" and "essentially biological processes" for the production of plants and animals. However through creative claims drafting, a patent may be broad enough to cover innovations in the production of new plant varieties or specific genes and their corresponding traits. This matter was considered by the Enlarged Board of Appeal of the European Patent Office in the landmark *Novartis* Case (see Llewelyn, 2000b).

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 European Patent Office 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 (NOVARTIS/Transgenic plant, T1054/96).

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.

An interesting question, raised by this case is the continuing role of PVR protection in the modern world of genetic engineering. To what extent will a sui generis system for the protection of plant varieties secure the rights of plant breeders in the face of innovations in patent law? To what extent ought PVRs be harmonised with patent rights? Given the developments in modern biotechnology, Farmers' Rights must be seen both in the context of patents as well as PVR protection.

7.2 Modalities for the Enactment of Farmers' Rights

Article 9.2 obliges the Contracting Parties to the International Understanding "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 International Undertaking leaves open the legal context within which Farmers' Rights are to be enacted. Obviously for the greatest efficacy, national Farmers' Rights legislation should be obliged as an internationally binding obligation. Article 9.1 identified farmers in "centres of origin and crop diversity" to be the particular beneficiaries of Farmers' Rights. It will be of little assistance to those farmers if the countries of exploitation, provide no recognition of those rights.

There are at least five possible legal contexts within which Farmers' Rights might be enacted: (a) biodiversity law; (b) intellectual property law; (c) traditional knowledge law; (d) human rights law; or (e) *sui generis* legislation.

7.2.1 Biodiversity Laws

An obvious vehicle for the enactment of Farmers' Rights legislation is pursuant to the Convention on Biological Diversity (CBD). The CBD, and the associated Rio Declaration on Environment and Development and Agenda 21, represent an attempt to establish an international programme for the conservation and utilization of the

world's biological resources (McConnell, 1996) and for the "fair and equitable sharing" of the benefits arising from the utilisation of genetic resources (Art.1). The developing countries of the South, the "centres of origin and crop diversity", sought to use the CBD as a means of bargaining access to their genetic resources for royalties, technology and research data. Thus the CBD contains articles on access to genetic resources (Art. 15); access to and the transfer of technology (Art.16); informed consent and the distribution of benefits of biotechnological innovations (Art.19). The industrialised group of countries, obviously the principal source of biotechnological innovation, insisted that the CBD did not conflict with intellectual property rights. Thus for example, Art. 16 (2) contains the statement that "In the case of technology subject to patents and other intellectual property rights, such access and transfer shall be provided on terms which recognize and are consistent with the adequate and effective protection of intellectual property rights".

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.

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". 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 (Glowka, 1998 at 4). This material would obviously fall within the sorts of endowments which would be embraced by the contributions of farmers.

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 (See Yusuf, 1995). Since these collections are invariably made up of germplasm contributed by traditional farmers, Farmers' rights could be built into the rules for the utilization of national *ex situ* collections.

Article 15(4) of the CBD envisages that where access is granted to genetic resources, this will be subject to mutually agreed terms. Currently the conventional form of access agreement is the Material Transfer Agreement (MTA) (See Cohen et al, 1998). Article 15(5) requires access to genetic resources to be subject to the "prior informed

consent" of the Contracting Party providing those resources, unless it waives that right. It has been suggested that the mutual agreement on access terms could be part of a larger biodiversity access determination regime administered by a designated competent authority (Glowka, 1997). This access regime could also deal with the issue of access to farmer conserved varieties and to the traditional knowledge of farmers and indigenous communities. A number of States already require bioprospecting to be subject to the grant of a permit. In this administrative process, full disclosure by the bioprospector is usually required (See Lairdl, 1993).

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. Each of these provisions can form a basis for Farmers' Rights legislation.

As is discussed below, benefit-sharing is one of the components of Farmers' Rights, introduced by, FAO Resolution 5/89. The draft text on his subject of the International Undertaking provides for benefit-sharing through the transfer of technology, capacity building and the exchange of information. (CGRFA/CG-1/99/TXT).

7.2.2 Intellectual Property Laws and Farmers' Rights

Farmers' Rights do not fit comfortably into an intellectual property context. Intellectual property rights are generally speaking, concerned with the stimulation of innovation by providing the incentive of prospective monopoly rights, for a limited period, as a reward for innovation. Farmers' Rights, on the other hand, are a retrospective reward, of unlimited duration, for the conservation of plant genetic resources.

The beneficiaries of intellectual property rights are identifiable inventors or innovators, whereas Farmers' Rights enure to communities of traditional farmers, or those entities which represent them. In the case of Farmers' Rights, it is often difficult to identify the beneficiary community, where, for example, a landrace is found in a number of different *in situ* national locations, as well as in *ex situ* collections outside the country (Eg see FAO, 1994, para.38).

The subject matter of each of the conventional categories of intellectual property right protection is precisely defined, whereas Farmers' Rights are attached to less specific incremental contributions to the innovation process. It is also pointed out that since the concept of Farmers' rights was originated as a counterbalance to the intellectual property system, it would be illogical to incorporate those rights within the intellectual property system (Correa, 2000b at 20).

The principal advantage which the international intellectual property system has for the enactment of Farmers' Rights, is that it has attracted the subscription of a wider group of countries than has the biodiversity rights system. Subscription to the Agreement on Trade Related Intellectual Property Rights (TRIPs) is mandatory for countries wishing to become members of the World Trade Organization. Thus, for example, the insertion of Farmers' rights into the TRIPs Agreement, will bind those countries, such as the USA, which have failed to ratify the CBD (See Blakeney, 2001c).

Within the TRIPs Agreement, the most obvious Articles within which to insert a Farmers' Rights regime are those dealing with patents, as well as article 27.3.(b) which obliges Members to protect plant varieties, through a patent or through a *sui generis* regime, or through a combination of both.

A number of possible models have been suggested. For example, at a the meeting of the Non-Aligned and Developing Countries at New Delhi on 29-31 January 1999, it was suggested that amendments be made to the patent provisions of the TRIPs Agreement, requiring patent applications to include:

(i) disclosure of all places of origin in the material/knowledge used in the application;
(ii) disclosure of all communities/persons of origin;
(iii) proof of consent having been obtained from the community/persons of origin;
(iv) proof of benefit-sharing arrangement having been entered into with the community/persons of origin…;
(v) disclosure of any previous rejection of application, in the country or other jurisdictions;
(vi) prior public notice in all relevant languages in the places or communities of origin (Blakeney, 1999a).

It also recommended for the inclusion of a comprehensive code of provisions protecting Farmers' Rights in national patent laws, with the establishment of a gene fund, "derived from fees and other levies on plant breeding and the seed industry" to support in-situ farmers' conservation.

A *Communication* to the TRIPs Council from Kenya, on behalf of the African Group, to assist the Preparations for the 1999 Ministerial Conference of the WTO (WT/GC/W/23, 5 July 1999), proposed that "after the sentence on plant variety protection in Article 27.3(b) of the TRIPs Agreement, a footnote should be inserted stating that any sui generis law for plant variety protection can provide for:

(i) the protection of the innovations of indigenous and local farming communities in developing countries, consistent with the Convention on Biological Diversity and the International Undertaking on Plant Genetic Resources;

(ii) the continuation of the traditional farming practices including the right to save, exchange and save seeds, and sell their harvest;

(iii) preventing anti-competitive rights or practices which will threaten food sovereignty of people in developing countries, as is permitted by Article 31 of the TRIPS Agreement."

At the third session of the WIPO Standing Committee on the Law of Patents, held in Geneva, September 6-14, 2000, the delegation of Colombia proposed the introduction into the proposed Patent Law Treaty, an article which provided that:

1. All industrial protection shall guarantee the protection of the country's biological and genetic heritage. Consequently, the grant of patents or registrations that relate to elements of that heritage shall be subject to their having been acquired made legally.
2. Every document shall specify the registration number of the contract affording access to genetic resources and a copy thereof whereby the products or processes for which protection is sought have been manufactured or developed from genetic resources, or products thereof, of which one of the member countries is the country of origin.

To facilitate progress on the procedural aspects of patenting, which was the primary objective of the Treaty, the source country question was referred to an expert group for further consideration. This issue is currently under consideration by the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore, established by the General Assembly of WIPO in September 2000.

7.2.3 Traditional Knowledge and Farmers' Rights

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

> to establish a process to empower indigenous peoples and their communities' through measures that include:
> - recognition of their values, traditional knowledge and resource management practices with a view to promoting environmentally sound and sustainable development;
> - enhancement of capacity- building for indigenous communities based on the adaptation and exchange of traditional experience, knowledge and resource-management practices, to ensure their sustainable development;
> - establishment, where appropriate, of arrangements to strengthen the active participation of indigenous peoples and their communities in the national formulation of policies, laws and programs relating to resource management and other development processes that may affect them.

The Preamble to the CBD recognised the

…close and traditional dependence of many Indigenous and local communities embodying traditional lifestyles on biological resources, and the desirability of sharing equitably arising from the use of traditional knowledge, innovations and practices relevant to the conservation of biological diversity and sustainable use of its components.

Article 8(j) of the Convention required each signatory

…subject to its national legislation, respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity and promote their wider application with the approval and involvement of the holders of such knowledge, innovations and practices and encourage the equitable sharing of the benefits arising from the utilization of such knowledge, innovations and practices.

The provisions of Art.8(j) require implementation through national legislation. In order to ensure that the requisite national legislation is implemented globally, indigenous peoples have reluctantly turned to the TRIPs Agreement as the medium for this implementation. On 25 July 1999 a federation of indigenous peoples groups issued a statement for the purposes of the TRIPs review. The Statement commences with the observation that "Humankind is part of Mother Nature, we have created nothing and so we can in no way claim to be owners of what does not belong to us. But time and again, western legal property regimes have been imposed on us, contradicting our own cosmologies and values." It expresses concern that Article 27.3(b) "will further denigrate and undermine our rights to our cultural and intellectual heritage, our plant, animal, and even human genetic resources and discriminate against our indigenous ways of thinking and behaving."

The Statement drew the distinction between private proprietorial rights and. "Indigenous knowledge and cultural heritage [which] are collectively and accretionally evolved through generations…The inherent conflict between these two knowledge systems and the manner in which they are protected and used will cause further disintegration of our communal values and practices

The Statement pleaded for a legislative structure which "Builds upon the indigenous methods and customary laws protecting knowledge and heritage and biological resources" and which prevents the appropriation of traditional knowledge and integrates "the principle and practice of prior informed consent, of indigenous peoples' as communities or as collectivities".

This Statement was picked up by a submission of Cuba, Honduras, Paraguay and Venezuela to the TRIPs Council (WT/GC/W/362, 12 October 1999) which stated that these countries "consider it fair to recognise the specific contribution of indigenous and tribal peoples and local communities to the cultural diversity and social and ecological harmony of mankind".

Responding to these developing country initiatives, the USA has urged that an effective sui generis system should clearly identify: (a) the subject matter of protection; (b) any limitations to the rights which will be granted under such a system;

and (c) the legal remedies available to rights holders (IP/C/W/209, 20 September 2000). In relation to a sui generis system for the protection of plant varieties, the US submission was that all plant varieties should be covered, with the objective of encouraging the development of new varieties from the widest possible range of genera and species. This submission also recommended confining this system of protection only to breeders or others specifically entitled through contract law or succession. The US submission was unsympathetic to the claims of indigenous people for the protection of oral knowledge and practices, because of the inaccessibility of this information beyond the relevant indigenous community.

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

The question of the protection of traditional knowledge in an intellectual property context has been a continuing concern of the the World Intellectual Property Organization (WIPO) (See Blakeney, 2000d). Since 1996, number of meetings and fact finding missions had been organized by WIPO to investigate the issue of intellectual property protection and traditional knowledge. In a Note to WIPO, 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." (WIPO Doc. WO/GA/26/9). 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."

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.

Finally, it was suggested that in concert with the secretariat of UPOV, the Committee could embark on the exploration of possible options for defining *sui generis* systems for the protection of genetic resources and biodiversity.

At the WIPO General Assembly, in late 2000, Member States agreed to 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: (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. These were adopted by the Committee at its inaugural meeting in May 2001.

In November 2000, WIPO convened an Inter-regional Meeting on Intellectual Property and Traditional Knowledge at Chiangrai, Thailand to provide an opportunity to developing countries to contribute to the activities of the Intergovernmental Committee. The meeting recommended that governments identify, catalogue, record and document genetic resources and traditional knowledge and that national mechanisms be established to regulate access to and benefit sharing in genetic resources and the protection of traditional knowledge and folklore.

As can be seen above, the discussion of traditional knowledge in the various international arenas, ranges much further than the territory claimed for Farmers' Rights. In particular, much of the debate on traditional knowledge has focussed upon the medicinal and industrial uses of plant genetic resources. To avoid confusion, it is probably better to consider the protection of the traditional agricultural knowledge of farmers, traditional communities and indigenous peoples in a more specific Farmers' Rights regime.

7.2.4 Human Rights Law

The World Food Summit, held in Rome in 1996 "reaffirmed the right of everyone to have access to safe and nutritious food consistent with the right of everyone to be free from hunger" (See Mishra, 2001). The perceived transcendental impact of the global intellectual property regime upon all aspects of human enterprise has caused questions to be raised about the human rights implications of intellectual property. In its Report, *Human Rights and Human Development*, the UNDP suggested that aspects of the TRIPs Agreement might be inconsistent with the International Covenant on Economic, Social, and Cultural Rights and the International Covenant on Civil and Political Rights (UNDPk, 2000, 83-88).

On 17th August 2000 the UN Sub-Commission for the Protection and Promotion of Human Rights , noting that

> …actual or potential conflicts exist between the implementation of the TRIPs Agreement and the realization of economic, social and cultural rights in relation to, inter alia, impediments to the transfer of technology to developing countries, the consequences for the enjoyment of the right to food of plant variety rights and the patenting of genetically modified organisms, 'bio-piracy' and the reduction of communities' (especially indigenous communities') control over their own genetic and natural resources and cultural values, and restrictions on access to patented pharmaceuticals and the implications for the enjoyment of the right to health,

adopted a resolution calling into question the impact of the TRIPs Agreement on the human rights of peoples and communities, including farmers and indigenous peoples worldwide (UN Commission On Human Rights. 2000). The resolution noted "the apparent conflicts" between the intellectual property rights embodied in the TRIPs Agreement and international human rights law, particularly that "the implementation of the TRIPS Agreement does not adequately reflect the fundamental nature and indivisibility of all human rights, including the right of everyone to enjoy the benefits of scientific progress and its applications, the right to health, the right to food, and the right to self-determination" (Art.2). The resolution reminded "all Governments of the primacy of human rights obligations over economic policies and agreements" (Art.3).

The resolution did nor specifically address the issues of intellectual property, food security and Farmers' Rights, beyond urging the Conference of Parties to the Convention (COP) on Biological Diversity to consider human rights principles and instruments in undertaking its assessment of the relationship between biodiversity concerns and intellectual property rights, in general, and between the Convention on Biodiversity and TRIPs in particular. (Art.13)

At the TRIPs Council meeting held on 21 March 2000, the Chair set out a list of issues to structure discussions on the review of Article 27.3(b) of the TRIPs Agreement. The list included:
- Ethical issues relating to 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.

In response to this list, Brazil issued a paper suggesting that "moral and ethical consequences of inventions are better dealt with directly- that is, by inhibiting the development of the technologies themselves instead of creating obstacles to their patentability." (IP/C/W/228, 24 November 2000). Thus, it was recommended that "whenever a Member considers that some specific technologies related to patents on technology are contrary to ethical, cultural or religious standards, Article 27.3(b) should consider the possibility of providing flexibility for Members to limit or to deny intellectual property rights over such technologies, in order to prevent that their development is encouraged."(para.6).

7.2.5 Sui Generis Legislation on Farmers' Rights

The final suggestion for the enactment of Farmers' Rights is as *sui generis* legislation. This legislation could incorporate the biodiversity, intellectual property, traditional knowledge and human rights elements mentioned above. Given the difficulties which are being experienced with the various proposals for the modification of Art.27.3(b) the TRIPs Agreement, which merely refers to the *sui generis* protection of plant varieties, there would seem to be substantial political obstacles to the promulgation of an international convention dealing with Farmers' Rights.

The softest international legislative option, is the establishment of an international fund to facilitate: the conservation and sustainable use of plant genetic resources, and traditional farmers' knowledge; to ensure access to new technologies and equitable sharing of benefits derived from the products obtained through the use of plant genetic resources for the benefit of present and future generations of farmers; and to

make appropriate efforts to mobilize adequate financial resources to support farmers' activities to conserve and use sustainably plant genetic resources for food and agriculture (Correa, 2000b).

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 (reproduced at Annex II), which was adopted by the OAU, Heads of States Summit at Ouagadougou in June 1998, adopts a sui generis regime based on UPOV 1991 (see Kongolo, 2000). However, most national statutes prefer access legisaltaion 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;)

Typical of this hybrid legislation is the African Model Law, which is divided into seven Parts:

Part I Objectives

Part II Definitions and Scope

Part III Access to Biological Resources

Part IV Community Rights

Part V Farmers' Rights

Part VI Institutional Arrangements

Part VI Plant Breeders' Rights

The African Model Law lists 11 objectives, of which protecting the rights of local communities, including farmer communities and breeders, by promoting fair and equitable sharing of benefits and the prior informed consent of the community are key.

The Law applies to biological resources in both *in situ* and *ex situ* conditions; the derivatives of these resources; community knowledge and technologies; local and indigenous farming communities and plant breeders. Any access to the biological resources of local communities is conditional to the prior informed and written consent of the local community. The following rights of local and traditional communities are recognised:

- the rights of communities over their biological resources;
- the right to benefit collectively from the use of their biological resources;
- their innovations, practices, knowledge and technology, acquired through generations;
- the right to benefit collectively from the utilisation of their innovations, practices, knowledge and technologies;

- the right to use their innovations, practices, knowledge and technologies in the conservation and sustainable use of their biological diversity.
- The exercise of collective rights as legitimate custodians and users of their biological resources.
- The right to prohibit any access to their biological resources, innovations, practices, knowledge and technologies where such access will be detrimental to the integrity of their natural or cultural heritage.

The African Model Law does not define "local community", however, this term is defined in the Indian Community Intellectual Property Rights Act as "a group of people having a long-standing social organization that binds them together, including indigenous peoples, farmers' communities and local populations".

In relation to benefit sharing the African Model Law provides "the State and the community or communities shall be entitled to a share of the earning derived from when any biological resource and/or knowledge collected generates, directly or indirectly, a product used in a production process." The Indian legislation goes further in providing for the collection and distribution of revenues to: the community or to an organization duly representing the community. Where representative bodies do not exist, the state can act as public trustee for payments. The Indian law also requires that revenues received by the state should be spent on the protection, development and maintenance of community genetic resources.

The definition of Farmers' Rights in the African Model Law is a statement of the rights which are enumerated in Article 10 of the International Understanding.

The plant breeder's rights which are contained in the African Model Law are subject to the following exceptions:

"…any person or farmers' community may:

a) propagate, grow and use plants of that variety for purposes other than commerce;

b) sell plants or propagating material of that variety as food or for another use that does not involve the growing of the plants or the propagation of that variety;

c) sell within a farm or any other place at which plants of that variety are grown any plants or propagating material of that variety at that place.

d) use plants or propagating material of the variety as an initial source of variation for the purpose of developing another new plant variety except where the person makes repeated use of plants or propagating material of the first mentioned variety for the commercial production of another variety.

e) sprout the protected variety as food for home consumption or for the market.

f) use the protected variety in further breeding, research or teaching.

g) obtain, with the conditions of utilization, such a protected variety from genebanks or plant genetic resources centres."

Farmers are also free to “save, exchange and use part of the seed from the first crop of plants which they have grown for sowing in their own farms to produce a second and subsequent crops”.

Correa (2000b at 37 -38) proposes the following options to reconcile IPRs with the farmers' right to save, sell and exchange protected seed:

> 1. distinguish between groupings of farmers with regard to the planting-back of protected material, on the basis of volume of output, size of landholdings, species concerned, etc. Thus, a broad farmers' exception may be granted to "primarily-subsistence farmers", or to "small" farmers who customarily reuse seed because they lack access to or financial resources for new seed every growing season. Large farmers in the commercial sector may be subject instead to other, more stringent, rules.
> 2. To exempt exchanges of seed that take place within the same community or with neighbours, and between farming communities.
> 3. To allow certain sales of seeds as propagating materials, for instance, those that take place within the farmers' customary market area.

As an effective *sui generis* PVP system must also take account of the remuneration of the breeder, Ghijsen (1998) suggests the creation of a public or private central fund from which the breeder is paid on the basis of the acreage of the protected variety which is grown by farmers.In exchange for the right of breeders to receive payments from the fund, farmers are permitted to save, exchange and trade the seed from the protected variety on a non-commercial basis. An alternative to the private right of seed saving is a system for the compulsory licensing of varities of open pollinated food crops.

The African Model Law also provides for the establishment of Gene Community Fund from royalties to be fixed by the National Competent Authority based on the gross value of the protected seeds. This fund is be used “to finance projects developed by the farming communities, ensuring equity for women, with or without the participation of experts to help them, aimed at solving their felt problems, including, but not restricted to, the development, conservation and sustainable use of agricultural genetic resources.”

The African Model Law is silent on the question of the participation of farmers in decision making, which is one of the components of Farmers' Rights, according to draft Article 10.2 of the international Undertaking. The Philippines Executive Order No. 247, by way of example, requires the rights of indigenous and local communities to be taken into account with regard to informed consent procedures. Farmers' participation in decision-making will ultimately be dependent upon the nature of the relations between local, indigenous and farming communities, on the one hand, and national governments, on the other.

Additional matters which have been recognised by commentators are:

- the particular problem of material which comes from more than one country, which it is suggested can be dealt with through bilateral or multilateral arrangements (Swaminathan, 1998).

- Correa (2000b at 22-23) suggests that national legislation could be promulgated to provide assistance to farmers and (traditional) farming communities, especially in areas of origin/diversity of plant genetic resources, in contributing to the evolution, conservation, improvement, evaluation and sustainable use of plant genetic resources for food and agriculture, through the participation in and establishment or strengthening of appropriate arrangements, and the participation of farmers and (traditional) farming communities therein such as: germplasm programmes and initiatives that promote the use of, and research into, crops which are not widely used.
- He also suggests (at 23) measures for credit facilities and market provisions governing farmers' access to plant genetic resources for enhancing traditional genetic resources, development and the exchange systems through, *inter alia,* the removal of financial and market barriers against such systems, for conservation, development and sustainable use, and transfer of technology that protect, integrate, enhance and develop traditional farmers' knowledge, know-how and practices. The African Model law proposes a royalty-based system for remunerating farmers. Other modalities include: taxes on seed sales, collection fees (for materials held *in situ*) and access fees (for materials held *ex situ*) (Correa 2000b at 30).

ANNEX I References

ANNEX II States party to the International Convention for the Protection of New Varieties of Plants

ANNEX III African Model Legislation for the Protection of the Rights of Local Communities, Farmers and Breeders, and for the Regulation of Access to Biological Resources