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### SOVEREIGN AND PROPERTY RIGHTS OVER PLANT GENETIC RESOURCES

by

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This background study paper is one of a number prepared at the request of the Secretariat of the FAO Commission on Plant Genetic Resources, to provide a theoretical and academic background to economic, technical and legal issues related to the revision of the International Undertaking on Plant Genetic Resources. The study is the responsibility of the author, and does not necessarily represent the views of the FAO, or its member states.

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For reasons of economy, the paper is available only in the language in which it was prepared.

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## Introduction

The international community has made considerable progress in developing a framework for the conservation, sustainable use and access to plant genetic resources. The International Undertaking on Plant Genetic Resources (adopted by FAO in November 1989)<sup>1</sup> laid down the basic principles on the matter. The Convention on Biological Diversity (June 1992) went a step further by establishing rules of a binding nature, which apply to resources held in their natural habitats as well as to *ex situ* collections acquired in accordance with the Convention. More recently, the FAO Conference adopted an International Code of Conduct for Plant Germplasm Collection and Transfer, which contains rules on the granting of collectors' permits and on the responsibilities of collectors, sponsors, curators and users of plant germplasm.

The development of the just referred international framework has been parallel to a trend towards the extension of intellectual property rights to living forms, including plants as such, plant varieties, and their genetic information. The patentability of plant genetic materials, broadly accepted in some countries, may nevertheless be limited in other countries, as discussed below. Many issues are still unresolved, and subject to considerable debate.

These two parallel processes of law-making have raised substantial questions relating to the nature of the rights over plant genetic resources and to their implementation. What does the existence of sovereign rights, as recognized by the International Undertaking and by the Convention on Biological Diversity mean? Are plant genetic resources, particularly those held in *ex situ* collections, subject to ownership or to other types of rights? What is the relationship between the property of the resources as physical entities and intellectual property rights that may be claimed on the genetic information they contain? May "informal" innovations be subject to intellectual property rights?

These are some of the questions addressed in this paper. Section 1 deals with the concept of sovereign rights and with its application to plant genetic resources. It considers, in particular, the provisions in this respect of the International Undertaking and of the FAO Code of Conduct for Plant Germplasm Collection and Transfer, as well as of the Convention on Biological Diversity. References to national constitutions and legislation is also made.

Section 2 discusses the applicability and extent of intellectual property rights over plant genetic resources. It also considers the different forms of protection available and the relevant international conventions. Trends on this matter in national legislations are briefly analyzed, as well as the contents of the TRIPs<sup>2</sup> Agreement for the protection of geographical indications and plant-related inventions.

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1 The text of the Undertaking was supplemented and clarified by Resolutions 4/89, 5/89 and 3/91).

2 "Trade-Related Aspects of Intellectual Property Rights", adopted as a component of the Final Agreement of the Uruguay Round.

Section 3 contains a brief discussion on the so-called “informal” innovations and on the implementation of “farmers’ rights” at the national and international level. Finally, section 5 presents the main conclusions of the study.

## **1. Sovereign rights**

### **1.1 Scope and extent of rights**

The existence of sovereign rights over a Nation’s territory, including its natural resources, is a well established principle in international law<sup>3</sup>. This principle means that a State has the power and jurisdiction to establish how the resources and assets (tangible and intangible) existing in its territory are distributed, used and eventually subject to property rights. In accordance with political and social conceptions, different solutions - as history shows - may be adopted with regard to land, mineral and other natural resources, capital and intangible assets.

Private property today prevails as the basic feature of most legal systems in the world. States, however, often retain certain goods under their control. Thus, in some countries the States have declared public property over mineral resources. Rivers and lakes are also generally subject to public property rights. States hold property subject to private law as well, such as with respect to land and other goods without an identified owner. Moreover, in federal States property (e.g. in relation to mineral resources) may be divided between the Federal State and the provinces.

Public property may be declared and exercised with respect to quantified and individualized goods, or with regard to an undetermined amount of resources belonging to a defined category. This is the case of public property established, for instance, over water and, in some countries, with respect to oil reserves existing in the State’s territory. All living matter under national maritime jurisdiction have also been declared public property and its exploitation subject to State concessions (Laquis, 1979, p. 476).

When the issue of property rights in connection with plant genetic resources is dealt with, a distinction should be made between the rights over a physical entity as such (physical property) and over the genetic information<sup>4</sup> contained in said resources (intangible property). It is in the latter where the real value of the resources lies and where the legal problems are particularly complex.

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3 Resolution 1803 of the U.N General Assembly stated, in 1962, that due care should be taken “to ensure that there is no impairment, for any reason, of the State’s sovereignty over its natural wealth and resources”. See also Principle 21 of the U.N. Conference on the Human Environment (Stockholm, 1972), which was reproduced by article 3 of the Convention on Biological Diversity (as quoted below).

4 The genetic material is composed of a combination of genes (genotype) which determines the physical and functional characteristics of the plant. The information related to such a material and to its expression (phenotype) is the relevant subject matter in terms of intellectual property rights).

With respect to physical property, plant genetic resources may be subject to private or public property rights. Property may be derived from the ownership of the land where plants are located, as a result of the application of the traditional law principle in accordance to which everything adhered or which is destined to be adhered to the land belongs to the landowner. Once separated from the land, the plants (or parts thereof) become subject to their own ownership regime as moveable property, including when they are transported outside the original land or to a different country.

The concept of physical property, though applicable to living entities - including animals - has been developed since Roman times having in view the protection of non-living matters. That concept provides an imperfect basis for regulating rights over plant materials which may be found in various places at the same time and which may be reproduced naturally or by cultivation. It leaves various issues without appropriate solution. Thus, the exclusive rights conferred by physical property would not prevent a person different from the owner to appropriate an identical or similar object, or to reproduce and use it. The *ius exclusivum* can not be effectively translated into a *ius excluendi* like in the case of property over inert subject matter (Bergmans, 1991, p. 398).

The issue of the intangible content of plant genetic resources (i.e. their DNA, gene and genotype information) requires a deep analysis. Except if otherwise established by law, such an information is normally deemed a component of the “public domain” (or a *res communes*) irrespective from the physical property that may be exercised over individuals carrying it. This is a result of the very nature of knowledge as a “public good” which may be simultaneously used by many without added costs and without reducing its availability to others<sup>5</sup>.

“Public domain” means in this context that the concerned knowledge may be used by anybody (nationals or foreigners), without any restriction. In other words, it does not mean that said knowledge is the “public” property of a particular State, but a good freely and internationally available.

The principle of “public domain” certainly allows for derogation by specific regulations, notably by the introduction of intellectual property rights as a mechanism for creating private rights. The establishment - or not - of intellectual property rights is one of the manifestations of sovereign rights, subject however - as indicated below - to the international conventions entered into on the matter.

An additional distinction which is relevant to treat the intangible property of plant genetic resources, is whether wild or domesticated plants are involved<sup>6</sup>.

The legal treatment of wild plant genetic resources is considerably unexplored yet. Within the sovereign rights of a State, the law may, for instance, establish that newly discovered plant genetic resources be declared a public property (Sedjo, 1988). They may also be deemed subject to the private property rights, such as landowners (as an extension of the already mentioned principle

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5 In economic terms, this characteristic is described as “non-rivalry”.

6 As elaborated below, the case of domesticated plants requires a further differentiation between landraces or “folkseeds”, on the one side, and “modern varieties” which are the result of formal breeding processes, on the other.

according to which plants legally are accessories to the land). This solution would certainly lead to extremely complex problems, since the new discovered specimen will very rarely be confined to a given property. The appropriation of wild resources may also be established to the benefit of discoverers, or regulated in a way similar to the case of harvest of wild animals, including user fees in favour of local and land owners (Reid et al, 1993)<sup>7</sup>.

In sum, legal alternatives within the sovereign power of a States to determine the legal treatment of plant genetic resources are numerous. However, the establishment of property or other rights in relation to plant genetic resources - as well as with respect to other goods - is limited by the nature of the (tangible/intangible) goods at stake. The freedom to legislate is also subject to eventual obligations internationally contracted by States. These limitations are briefly dealt with below.

## 1.2 Limitations

The first type of limitation stems from the need under law principles, of defining, on the one side, the subject matter and, on the other, the title-holder of rights. Ownership rights, in particular, require a clear identification of the tangible or intangible goods to which it refers. Proposals relating to the appropriation of plant genetic resources under the intellectual property system, are conditioned by the technical possibility of describing said resources with sufficient specificity.

Today there are available techniques<sup>8</sup> to this end, which permit to identify genetic materials and even to trace the expression of defined genes when introduced in different varieties. However, most of the available plant diversity has not been characterized yet by these methods. In addition, a given DNA sequence may exist in materials collected in multiple locations and, therefore, there is no safe means to trace the origin of a variety in order to eventually confer rights to a unique “original” innovator. Moreover, often a variety combines a multiplicity of landraces collected in different countries<sup>9</sup>. All this constitutes an important limitation for the implementation of any scheme intended to compensate farmers or countries for the conservation and continued improvement of landraces on a basis similar to some form of intellectual property right.

A second kind of limitation arises out from the fact that the distribution of plant genetic resources is not governed by national boundaries. Though rights exercised with respect to such resources as physical entities (property of the plants or of parts of them as such) create no difficulty and are subject to national jurisdiction, the situation varies when rights are claimed with regard to the genetic information of resources which may be available in different countries (like in the case of major crops). Unlike the case of the property on, say, an apple, that is limited to one holder, property relating to intangibles extends to any individual carrying the characteristics that are claimed as proprietary.

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7 The appropriability of wild resources seems to be mostly relevant for plants which may be used for medicinal purposes, rather than for food. In the latter case, some degree of domestication has taken place all over the history, although a large part of landraces and even materials deposited in gene banks have not been fully catalogued and described.

8 They include methods of DNA sequencing, polymerase chain reaction (PCR) and restriction fragment length polymorphisms (RFLP).

9 The IRRI IR 72 rice variety, for instance, is reported to incorporate more than twenty landraces originating from different countries (The Keystone Center, 1991).

Finally, a third type of limitation is a result of commitments made by States as members of the international community, and emerging either from voluntary instruments or from obligations under treaties to which the States have adhered to. The extent of these limitations are presented in subsequent subsections with respect, in particular, to the access to plant genetic resources and the provision of intellectual property rights.

### **1.3 Sovereign rights over plant genetic resources in international agreements**

#### **i) The International Undertaking**

The first international agreement to recognize States' sovereign rights with respect to plant genetic resources was the FAO International Undertaking on Plant Genetic Resources, as clarified by Resolution 3/91, which endorsed the concept that "nations have sovereign rights over their plant genetic resources".

As drafted, the International Undertaking is based on the recognition of States' sovereign rights. But the States parties to the Undertaking<sup>10</sup>, have voluntarily accepted that such rights are limited by the right of other countries adhering to the Undertaking<sup>11</sup> to have "free access" to the plant genetic resources residing in their territory. States agreed:

"To allow access to samples of such resources, and to permit their export, where the resources have been requested for the purposes of scientific research, plant breeding or genetic resource conservation. The samples will be made available free of charge, on the basis of mutual exchange or on mutually agreed terms." (article 5 of the International Undertaking).

In addition, in accordance with Resolution 4/89,

"A state may impose only such minimum restrictions on the free exchange of materials covered by Article 2.1.(a) of the International Undertaking as are necessary for it to conform to its national and international obligations" (Article 2 of the Agreed Interpretation).

It should be noted that under the above provisions, countries adhering to the International Undertaking agreed to confer access to the samples only for specified purposes, i.e., scientific research, plant breeding or conservation. This clearly excludes access with an aim to reproducing the materials for commercial purposes, such as for propagating seeds.

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10 Given the non-binding nature of the International Undertaking, these countries should be deemed to include all those members to the FAO Conference which have voted the approval of the Undertaking or of its Annexes.

11 In accordance with provisions 5.b) of Resolution 4/89, the benefits to be derived from the Undertaking are "part of a reciprocal system, and should be limited to countries adhering to the International Convention".

The principle of “free access” in this context does not mean, on the other side, “free of charge”, as clarified by Article 5.a of Resolution 4/89. Under these provisions countries could not, in principle, prevent access to plant genetic resources residing in their territories, but they could certainly establish the conditions whereunder such access could take place. This point, as discussed below, has now been clarified by the Convention on Biological Diversity, which makes access (although not restricted to non-commercial purposes) conditional upon “mutually agreed terms” and the sharing of benefits obtained as a result of the transfer.

One of the immediate questions with regard to Article 5 of the International Undertaking, is what would occur in case the parties do not agree on the conditions for access to a certain resource. Which national or international authority might intervene in order to enforce the right of access? Given the voluntary nature of the International Undertaking, no mechanism is available to that end. Hence, the right of access provided for by the Undertaking constitutes a potential, but not necessarily enforceable, limitation to sovereign rights over plant genetic resources.

The International Undertaking does not prejudges, finally, with respect to the means of appropriation that countries, while exercising their sovereign rights, may establish in respect of plant genetic resources. It states that:

“Plant Breeders’ Rights, as provided for under UPOV (International Union for the Protection of New varieties of Plant) are not incompatible with the International Undertaking” (Article 1. of the Agreed Interpretation, Resolution 4/89).

No reference is made with respect to the compatibility of the Undertaking with the patenting of plant genetic resources. The granting of patent rights, in principle<sup>12</sup>, implies a restriction on the access to the protected materials - as discussed below - greater than in the case of breeders’ rights. The compatibility of the International Undertaking with patent rights is likely to be discussed in the framework of the ongoing process of the FAO Commission on Plant Genetic Resources. Divergences of opinion may be anticipated, since many developing countries seem to view patenting of plants and plant varieties as incompatible with a policy of development and sustainable use of plant genetic resources<sup>13</sup>.

#### **ii) Code of Conduct for Plant Germplasm Collecting and Transfer**

Relevant provisions of the Code of Conduct on sovereign rights over plant genetic resources are contained in articles 3.2 and 6.1:

“The code recognizes that nations have sovereign rights over their plant genetic resources in their territories and it is based on the principle according to which the conservation and continued availability of plant genetic resources is a common concern of humankind. In executing these rights, access to plant genetic resources should not be unduly restricted.” (article 3.2)

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12 An exception to this general principle is provided by the Mexican patent law, as revised in June 1991. It provides in cases of patents on living forms, for an exemption similar to the “breeder’s exemption” recognized under breeders’ rights systems.

13 See also section 2 below.

“States have the sovereign right, and accept the responsibility, to establish and implement national policies for the conservation and use of their plant genetic resources, and within this framework, should set up a system for the issuance of permits to collectors” (article 6.1)

Article 7 of the Code of Conduct further contemplates the right of the “permit issuing authority” to “grant or to refuse” a permit, and that collectors and sponsors should “undertake to respect the relevant national laws”. Article 8 spells out the conditions under which a permit for collection should be “expeditiously” issued, including any financial obligation to be met by the applicant.

The Code of Conduct thus reaffirms the States’s sovereign rights over plant genetic resources, and the commitment not to “unduly” restrict access to such resources. Like in the case of the International Undertaking, being of a voluntary character, the Code does not include mechanisms to ensure enforcement or dispute settlement.

### **iii)The Convention on Biological Diversity**

The Convention on Biological Diversity is also premised on the concept of sovereignty over genetic resources (not limited however to plants). Sovereign rights, as recognized under articles 3 and 15.1 of the Convention, are however limited by a number of obligations accepted by the parties to the Convention<sup>14</sup>:

“States have, in accordance with the Charter of the United Nations and the principles of international law, the sovereign right to exploit their own resources pursuant to their own environmental policies, and the responsibility to ensure that activities within their jurisdiction or control do not cause damage to the environment of other States or of areas beyond the limits of national jurisdiction” (article 3)

“Recognizing the sovereign rights of States over their natural resources, the authority to determine access to genetic resources rests with the national governments and is subject to national legislation” (article 15.1)

“Each Contracting Party shall endeavour to create conditions to facilitate access to genetic resources for environmentally sound uses by other Contracting Parties and not to impose restrictions that run counter to the objectives of this Convention” (article 15.2)

“Access, where granted, shall be on mutually agreed terms and subject to the provisions of this article” (article 15.4)

“Access to genetic resources shall be subject to prior informed consent of the Contracting Party providing such resources, unless otherwise determined by that Party” (article 15.5).

The right of access by other Contracting parties is, thus, dependent upon the conditions established by the legislation and competent authorities of each country and subject to the country’s

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14 *Brevitatis causa*, we only comment here the obligations relating to the access to genetic resources.

prior consent, provided further that “mutually agreed terms” are reached between the parties. The drafting of the obligation assumed in respect to access is loosely formulated as a “best efforts” obligation (“...shall endeavour to create conditions to facilitate...”, but there is a (negative) obligation “not to impose restrictions that run counter to the objectives of this Convention”. In other words, the right of access is not absolute and its exercise is subject to an explicit authorization from the requested country, but it is an enforceable right which can not be arbitrarily denied<sup>15</sup>. Unlike the International Undertaking and the referred Code of Conduct, the Convention provides for a dispute settlement mechanism, which may be put into operation to ensure the enforcement of the right of access and of other obligations set forth by the Convention.

Another obligation assumed by Contracting Parties is to provide, “... in the case of technology subject to patents and other intellectual property rights...”, for an “adequate and effective protection “ of said rights (article 16). This article may be read as requiring the patentability of genetic resources, but in fact only defines the conditions of protection if and when such a protection is conferred. As mentioned below, the TRIPs Agreement has also left countries with the freedom to extend or not patent protection to biotechnological inventions (except microorganisms and related processes).

#### **1.4 National laws**

Some countries have adopted explicit provisions which reflect the concept of sovereignty over genetic resources.

The Wild Life Protection law of Costa Rica (October 12, 1992), declared that all wild plants and animals are a “national patrimony” and required collectors to: submit an application for a license that details their collection plans; deposit voucher samples with the national collection; and, send copies of publications resulting from the work to the national library. Collection for non-scientific purposes requires a special license and must involve the use of public bids, concessions, or contracts.

Article 225, 1o.II of the Constitution of Brazil (adopted in 1988), refers to the preservation of “the diversity and integrity of the genetic patrimony of the Country” and empowers the authorities “to supervise the entities devoted to research and handling of genetic material”. The constitution further and more specifically declares as a “national patrimony” the “*Foresta Amazónica brasileira, a Mata Atlántica, a Serra do Mar, o Pantanal Mato-Grosense e a Zona Costeira*” (article 225, 4o).

A draft law submitted to the Argentine Parliament in 1991 proposed to declare all wild genetic resources “private goods” of the Federal States and of the Provinces, and to submit their exploitation to State concession (Draft law 57-D-91, submitted by Alvarez Guerrero, F. Storani and A Elías). This proposal has not received yet treatment by the Parliament. In India, a draft legislation on plant varieties protection provides that the National Bureau of Plant Genetic Resources “shall exercise rights on germplasm covering the whole range of plants of all genera and

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15 If the requested country has not legislated on the issuance of permits, the understanding could be, however, that said country “will not be able to deny access to genetic resources, if it can not invoke a regulation that justifies its decision” (Hendriks et al, 1993).

species in the Indian territory under the sovereign right, exercised on behalf of the Government of India” (article 7, chapeau).<sup>16</sup>

A more comprehensive gathering of information on national constitutions and legislations on this matter would be required in order to undertake a comparative law study. It may be assumed, however, that in a majority of countries no specific provisions have been adopted, and that the issue of property over genetic material resources would need to be considered under the applicable principles and regulations of each country. The implications of different legislative options should be further clarified and, on that basis, model provisions for national laws could be developed.

Such provisions should take the particular nature of plant genetic resources for food and agriculture into account, and eventually propose new concepts in order to deal with the complexity of the matter.

### 1.5 *Ex situ* collections

The issue of the legal status of the *ex situ* collections of germplasm has attracted considerable interest, particularly in view of the possibility of obtaining intellectual property rights over collected materials.

A FAO study (FAO, 1987) found in 1987 that

“the position with regard to the ownership of plant genetic resources in gene banks may be summarized as follows. The material held in Government gene banks or in those of public institutions belongs (subject to any specific exceptions) to the State or to individual public institution. In either situation, in practical terms, ownership and control are vested in the State. Only in a few instances is the precise question of legal title unclear. The situation with regard to the International Agricultural Research Centres is more unclear still. In this context may be viewed those gene bank which consider themselves the custodians or depositories of the germplasm held there. There are also, of course, *ex situ* collections of plant genetic resources held by private corporations, but little information about them is available. Since they are not under Government control, they fall outside the scope of this study”.

Though differences between common-law and continental law-countries exist with respect to the concept of property rights, in principle they are established only by law<sup>17</sup>. Property rights can neither be created nor derogated by private parties, and their definition and enforcement is one of the major attributes of sovereignty within the territory of each State. Therefore, the legal status of materials held in *ex situ* collections will depend primarily upon the principles of law and the legislation of the State where the collection is located.

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16 It should be noted that while this clause asserts sovereign rights, it does not provide for a specific solution with regard to the property of germplasm.

17 This principle is called the “*numerus clausus*” under continental law, indicating that property can only be created by law.

To what extent, however, could national regulations be applied with respect to collections held in a given country but originating - as generally is the case - from other countries and obtained under the principle of free exchange of germplasm? Though the physical property of the respective samples may be well established, the same does not apply to their intangible contents (which, in principle, belong to the “public domain”). Therefore if a State claims property rights over said samples and unjustifiably restricts access to them, the legitimacy of said restrictions would be questionable under the principles developed by the international community, as reviewed above.

The law of the State where the collections are located will also apply with respect to collections held in internationally supported centres, except where the materials have been acquired and are maintained under specific rules, for instance, in the framework of an international agreement. Between 1975 and 1990 IPBGR signed 219 agreements with genebanks to house base collections of specific crops, 53% of which with entities in developed countries, 24% with IARCs and 23% with entities in developing countries. However, the legal status of these agreements seems to be unclear, and in most cases have been concluded by the IBPGR with specific institutions (public or private) and not with the governments (Vellvé, 1994).

The CGIAR Centres have offered to place their collections under the auspices of FAO. The current understanding - as expressed in the model agreement to be established between FAO and said Centres - is that the latter hold the collected germplasm as “trustees” for the benefit of the international community, and hence they do not own it like other assets (Siebeck and Barton, 1991, p. 8). Such a trustee does not imply the transfer or recognition of legal ownership by the trustee in the property, since “the concept of trusts in international law is somewhat more diffuse and does not necessarily, and in the case of trust territories does not absolutely, imply transfer of legal ownership rights or sovereignty” (FAO, 1994, p. 2).

The Centres would not, in addition, claim legal ownership nor seek any intellectual property rights over collected germplasm or the related information, and will further ensure that entities receiving samples are bound by the same obligations (articles 3 and 10 of the proposed agreement).

## **1.6 Summary of section 1**

In sum, property over the materials held in a State’s territory will be subject to the law in force in that State, both in connection with the ownership of the physical entities as well as with the appropriability of the relevant genetic information via intellectual property rights. Physical ownership, as mentioned above, may be of a private or public nature. Intangible property may be ensured on the basis of intellectual property rights. However, if protection via intellectual property rights is not available or it is available but protection has not been claimed or has expired, the “intangible” content of the resources belong to the public domain, and is hence outside any possible appropriation<sup>18</sup>.

The principle of sovereign rights over genetic resources means that the State has considerable room to determine the legal framework applicable to them, subject to the limitations arising from the nature of the subject matter and from international law and principles. Sovereign rights should not be confused, in any case, with property rights, the availability and scope of which are to be

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18 An invention also enters the public domain when its content is made public by any means.

determined by national law. This applies to both germplasm conserved *in situ* conditions and in *ex situ* collections.

Property law, historically built up to deal mainly with inert matter, leaves many issues unclear when applied to living materials, particularly plant genetic resources. New legislative approaches that take the specificity of such resources into account need to be developed.

## **2. Intellectual property rights**

### **2.1 Intangible and physical property**

As discussed above, plant genetic resources (or certain categories thereof) may be the subject matter of public/private ownership rights, which in principle belong to the landowner, or to those who legitimately hold the plants or parts of them once they have been harvested or otherwise separated from the soil. These rights refer to the physical organisms and their parts as such.

Intellectual property rights confer rights of a different nature, though implications for the access to and use of the physical organisms may be comparable. Three main differences between ownership of an individual plant (or parts thereof) and intellectual property may be pointed out.

First, in the case of intellectual property rights, property is temporary (up to 20 years from application, in general for patents, and 20/25 years in accordance with UPOV, 1991 Act, for breeders' rights), while physical property is perpetual.

Second, intellectual property rights refer to the intangible content of goods or to processes. In the case of living forms, for instance, they may refer to the information contained in genes or other sub-cellular components, or in cells, propagating materials or plants. This does not imply the property on the individuals as such that carry on such an information, but the right to exclude third parties from producing or selling them. The "exclusive" rights of the title holder are exercised over the materials containing the protected information<sup>19</sup>, and in this way the production, storage, distribution and trade of certain materials is affected. In the case of breeders' rights, for instance, rights are exercised with respect to propagating materials<sup>20</sup>, while in the case of patents it may involve the plants as such or some of its components.

Third, intellectual property rights do not confer an "absolute" property in the sense that the property rights can only be exercised in countries where the respective title has been granted. Given that at least in the field of patents and breeders' rights the principle of "territoriality" applies, no protection exists - and innovations belong to the "public domain" - in countries where no registration has taken place.

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19 It should be noted that in the case of trade secrets, protection conferred is against acts contrary to honest commercial practices and that it does not entail an "exclusive" right. Trade secrets protection is particularly relevant for hybrid seeds. It is lost when there is public disclosure of the relevant information, for instance, when a company sells a bag that contains even a few seeds of the inbred parent.

20 UPOV Convention, as revised in 1991, allows member countries to permit the title holder to exercise his right in relation to the end-products made directly from protected varieties, whenever he had no reasonable opportunity to do it with respect to the harvested materials. See Subsection 2.3 below.

In economic terms, the effect of intellectual property rights is to transform a “non-rival public good”<sup>21</sup> (knowledge) into a good subject to private control. Scarcity is, then, artificially created by law in order to push prices up and, according to a general justification, reward the innovator<sup>22</sup>.

## 2.2 Trends in the patentability of plant genetic materials

Considerable - but not complete - agreement exists in industrialized countries with respect to the protection by intellectual property rights of biotechnology-related inventions. An accepted principle is that the fact that an invention consists of, is based on or employs living matter, is not a ground to exclude protection.

Legislation and case law have evolved during the last fifteen years, in parallel with the development of genetic engineering techniques and new applications for biotechnology. Such developments were triggered by the well known decision by the U.S Supreme Court in re Chakrabarty (1980). The patentability admitted for microorganisms *per se* was rapidly extended in the U.S to complex organisms, including plants and animals<sup>23</sup>.

A number of aspects of current trends in the intellectual property field are relevant for the issues discussed in this paper.

### 2.2.1 Patentability of naturally occurring substances

Legislative trends and case law are also converging in industrialized countries in connection to the appropriability via patent protection of materials existing in nature. In countries that are members to the European Patent Convention a patent can be granted, in principle, when a substance found in nature can be characterized by its structure, by its process of obtention or by other criteria, if it is new the sense that it was not previously available to the public. In accordance with the Guidelines of Examination of the European Patent Office:

“To find a substance freely occurring in nature is also mere discovery and therefore unpatentable. However, if a substance found in nature has first to be isolated from its surroundings and a process for obtaining it is developed, that process is patentable. Moreover, if the substance can be properly characterised either by its structure, by the process by which it is obtained or by other parameters... and it is ‘new’ in the absolute sense of having no previously recognised existence, then the substance *per se* may be patentable... An example of such a case is that of a new substance which is discovered as being produced by a microorganism”. (Part C (IV), 2.1)

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21 This concept means that the use by one individual of a certain goods does not reduce its value and usability by others.

22 For a review on economic literature on intellectual property, see Siebeck et al (1990).

23 A vast literature exists on the evolution of legal approaches on biotechnology in the United States. For a general view, see Bent, S., Schwaab, R., Conlin, D. and Jeffrey, D., (1991).

In the United States an isolated and purified form of a natural product is patentable in accordance with principles developed for chemical patents. The concept of “new” under the novelty requirement does not mean “preexisting” but “novel” in a prior art sense, “so that the unknown but natural existence of a product cannot preclude the product from the category of statutory subject matter” (Bent et al, 1991, p. 123). As a result of this interpretation, a very thin line separates invention from discovery, and many patents have been granted on purified or crystallized products obtained from a natural source of impure material. They have included, for instance, purified dextrose, pure carbon black in the form of porous pellets, synthetically produced vitamin B12, prostaglandin compounds, interferon and strawberry flavouring compositions.

In the case of Japan, a similar approach has been followed. In accordance with the Enforcement Standards for Substance Patents, patents can be granted on chemical substances artificially isolated from natural materials, when the presence of the substance can not be detected without prior isolation with the aid of physical or chemical methods.

### **2.2.2 Patentability of plant genetic resources**

#### **A) Genes, cells and processes**

No major differences exist in industrialized countries with respect to the patentability of microorganisms and of microbiological processes<sup>24</sup>. “Microorganisms” are generally deemed to include cells as well as sub-cellular components<sup>25</sup>.

Under this principle and the approach referred to in the previous subsection, the patenting of cells, sub-cellular components and genes, whether pre-existing or modified, has become possible. In the United States, for instance, genes that are engineered by mutagenesis or genetic engineering techniques, or even that had not been known to previously exist in nature are patentable (Bent et al, 1991, p. 276). Claims in these cases normally refer to an isolated DNA sequence, DNA constructs and new transformed plants derived from it, though claims often include natural DNA sequences without limitations.

An example of a claim to the gene itself is the glyphosate-resistant synthetase gene, which expressed in plants imparts protection from the herbicidal action of the glyphosate. One of the relevant claims reads:

“A DNA sequence of less than 5Kb having a structural gene coding for a glyphosate resistant 5-enolpyruvyl-3-phosphoshikimate synthetase”. (U.S Patent 4.535.060, issued August 13, 1985).

In other cases, patent claims refer to genetically engineered organisms, or to the vehicles for transferring foreign DNA. For instance a patent issued in 1983<sup>26</sup> reads as follows:

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24 There are, however, some exceptions. Thus, in Norway the Patent Office has interpreted the plant and animal variety exclusion to preclude protection for microorganisms, cell lines, and vira and plasmids. It is also uncertain whether RNA or DNA macromolecules are patentable (Bent et al, 1991, p. 514).

25 This includes human cells. For instance, the University of California at Los Angeles patented a cell line produced from a spleen removed from a leukaemia patient named John Moore.

26 U.S patent No 4.407.956.

“A plant cell from the family Cruciferae containing at least one recombinant Cauliflower mosaic virus capable of propagation and movement, said movement comprising replication and systemic infection, said virus or a parent thereof having received in vitro an insertion of foreign DNA at the intergenetic region between reading frames VI and I, a site non-essential to such movement” (U.S. Patent No.4,407,956 - issued October 4, 1983).

Patents have also been granted in the United States with respect to plant breeding processes, such as in the case of the Jones-Mangelsdorf patent for fertility restoration in male-sterile corn (*Zea Mays* L.) (Stiles, 1989, p. 35).

Table 1 includes a list of some patents issued in that country, after the landmark case in *Ex Parte Hibberd*, on plant cultivars and hybrids *per se*.

Table 1. Examples of utility patents issued in the United States
Sunflower ( <i>Helianthus annuus</i> L.) regeneration
Potato ( <i>Solanum tuberosum</i> L.) cultivar
Inbred corn line
Hybrid corn line
Tryptophan overproducer mutants
Mushroom ( <i>Agaricus bisporus</i> L.) mutants strains
Process producing odourless soybean
Bean ( <i>Phaseolus vulgaris</i> L.) plant having low pod detachment force
Squash ( <i>Cucurbita pepo</i> L.) cultivar
Tetraploid corn and method to produce
Process for microplant propagation
Herbicide resistance in tobacco ( <i>Nicotiana tabacum</i> L.)
Kiwi ( <i>Actinidia chinensis</i> Planch) fruit plant

*Source: Jondle, 1989, p. 8*

In Europe, microorganism and microbiological processes are also patentable. This has been interpreted in the sense of admitting patents relating to vector systems to introduce foreign DNA into plant cells, modified plant cells, tissue cultures, as well as processes of transforming plant cells and somatic cell hybridization techniques<sup>27</sup>.

## **B)Plants**

Unlike the case of microorganisms, in the case of plants (as well as animals) considerable differences still exist among national legislations, including among industrialized countries. While in the United States special patents (based on the Plant Patent Act of 1930), breeders rights and - since 1985 - utility patents are conferred on different types of plants, in European countries plant

<sup>27</sup> It should be noted that in many cases biotechnology-related inventions are claimed under a “product-by-process” format, given the intimate relationship between certain processes and the produced results and the extension of protection generally accorded to the products directly made by a patented process.

varieties and the essentially biological processes for their obtention are excluded from patent protection (by virtue of the European Patent Convention). The same applies to “animal races” (and the related process of obtention, if essentially biological).

Thus, in the United States patents have been granted which protect plants, seeds and tissue culture. For instance U.S. patent No 4.581.847, issued in 1986, included the following claims:

“XVIII. A maize plant capable of producing seed having an endogenous free tryptophan content of at least about one-tenth milligram per gram dry seed weight, wherein the seed having an endogenous free tryptophan content of at least about one-tenth milligram per gram dry seed weight.

XIX. A tryptophan overproducing maize plant capable of expressing a gene coding for an anthranilate synthase which retains from about 60 to about 80 percent of its activity in the presence of 5-methyltryptophan at a concentration of about 10<sup>-5</sup> M, wherein the plant is capable of transmitting the gene encoding the anthranilate synthase to its progeny.

XX. A maize plant derived from seeds deposited with In Vitro International, Inc. and Assigned IVI accession No. 10010.”<sup>28</sup>

In Europe, notwithstanding the prohibition to patent plant varieties, plant-related inventions have been admitted. On the one side, the exclusion of “plant varieties” (as well as of “animal races”<sup>29</sup>) has been construed as limited to cases where plants are characterized by the genetically determined peculiarities of its phenotype. Inventions which do not involve a varietal aspect of a plant are generally deemed patentable, including parts of a plant or uses of a variety<sup>30</sup>.

On the other side, the exclusion referred to essentially biological processes aims at excluding the protection of conventional breeding techniques. The patentability of a process for the production of plants has been admitted not only when such a process has been altered in its constituent parts, but also when the alteration lies in the special sequence of the process steps (such as in the *Lubrizol* case).

### 2.2.3 Scope of protection

Patent claims relating to plants may refer to a specific variety (e.g. “an inbred corn line having the designation HBA1”<sup>31</sup>), or to plant phenotypic or genotypic characteristics, as well as to a

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28 This and other examples of claims reproduced in this paper have been selected from materials presented in Bent et al, 1991. With regard to the maize tryptophan patent it is interesting to note that the original claims were not limited to maize, but they also recited other cereal crops such as rice, wheat, barley, sorghum and oats (ibidem, p. 229).

29 For the patenting of animals, a landmark case has been the European Patent Office decision to patent the “Harvard onco-mouse”.

30 It is also to be noted that in Belgium, France, Germany and Italy, the limitation to patent a plant variety applies to the extent that it is protectable under plant breeders’ rights. Plant varieties were generally deemed patentable in Europe until the 1950s.

31 U.S. patent 4.594.810, claim 1.

combination of both. A phenotypical claim may be made with respect to a particular morphological plant trait, which could also be claimed genotypically. Genetic factors or genotypes as such may be claimed, whether created by traditional breeding, mutagenesis or selection, or by genetic engineering (Seay, 1993, p. 69-71)<sup>32</sup>. Patents may also protect processes for making or using plants.

Patents covering genes are not generally confined to the sequence of a gene. The patent application

“typically claims first, a gene or protein, standing alone, corresponding to that sequence; second, a vector or plasmid incorporating the sequence; and, possibly, third, a plant (of a particular range of species) that has been transformed by means of such a vector (and the descendants of the transformed plant). Thus, the patent holder gains effective control over use of the specified gene in genetic engineering” (Barton, 1993, p. 14).

Considerable uncertainty and controversy exists over the scope of protection conferred by patents relating to plant resources. On the one side, Patent Offices in some countries seem to apply patent requirements to biotechnological inventions in a flexible way. Thus, the non-obviousness requirement has not prevented, for instance, the patenting of a method inhibiting genes in plants, despite an earlier disclosure of the same process for inhibiting genes in any organism.

On the other side, patent claims are generally drafted in functional or informational terms, rather than in structural terms, and inventions which embrace all ways of solving a problem are protected. Thus, the Hibberd patent described the increase in tryptophan content rather than particular genes and in this way,

“he has, in effect, patented all genes that allow for a higher tryptophan level gained through inheritance. This creates serious implications for continued progress in corn breeding, especially for this trait. Essentially then, we now have a situation in which no other breeder can use the high tryptophan variety as the parent of a new generation except by agreement with the patent holder” (Plowman, 1993, p. 35).

Another examples are offered by a patent granted to Plant Genetic Systems covering the introduction of Bt into most field crop, and an Agracetus patent claim, which refers to any genetic manipulation of cotton regardless of the cotton germplasm in use<sup>33</sup>. The Agracetus U.S patent No. 5.159.135 (27.10.92) protects:

a method to achieve genetic transformation of cotton plants and lines. Immature cotton tissues are genetically transformed in vitro, by Agrobacterium-mediated genetic transformation. The resultant cotton tissues are subjected to a selection agent or agents to screen for transformants.

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32 Claims by genotype may cover genes at a plant cell level (covering all plants including a cell with that gene), cytoplasmic traits, specific mutant alleles, and species of transgenic plants, among other possibilities.

33 Another example is a patent granted to Plant Genetic Systems covering the introduction of Bt into most field crops. Bt is the most commonly used bacillus to develop insect resistance.

The transformed cultures are then induced to commence somatic embryogenesis. One possible regime for generating such somatic embryos into whole cotton plants is disclosed.

Concern about claims that can extend to many varieties, or even to entire species, has been voiced by many experts and entities, including the American Seed Trade Association (ASTA) and the U.S National Wheat Improvement Committee (NWIC) (Schapaugh, 1989, p. 22 and Stiles, p. 40). An ASTA statement expressing the majority member viewpoint recommended with regard to the patenting of plants and their characteristics, the following:

“5. Patents for genetic components or characteristics of crops should be granted on the following basis:

- a) Only genetic components that directly serve to cause expression of useful characteristics in crops should be eligible for protection.
- b) Characteristics of crops should not be patented unless the direct genetic causative agent is identified and itself qualifies to be patented.
- c) Alternative genetic approaches to achieve the same characteristic or trait in crops shall not infringe a prior patent.

6. In recognition of the above, and subject to N<sup>o</sup> 7 below, there should be a legally established compulsory licensing system under which a person who develops a new, distinct variety that falls within the scope of a patent of another party shall have a right to commercialize the new variety, free of infringement, under a system that provides equitable compensation to the owner of the patent.

7. Provisions for compulsory licensing would apply when the scope of a product or process patent is so broad as to encompass within its scope varieties or parts of plants not yet developed. Examples of such patents would include patents with claims direct to:

- a) Characteristics of crops,
- b) Genetic components that act as agents for expression of characteristics of crops, or that serve to regulate or control further steps of synthesis of plant material or,
- c) Processes of genetic manipulation” (Schapaugh, 1989, p. 19)

In addition to the “horizontal reach” of patents across plant varieties and species which may sweep public germplasm into privately protected property, the “vertical reach” of protection of improved traits is also problematic. Depending upon the patent claims and their scope, “protection may reach back to unimproved germplasm contained in relatives of a patented cultivar. This vertical reach across generations presents a difficult situation, since previously undescribed parts of the publicly held lines may unknowingly be swept into the category of private property. This concern is also shared by many of the public plant breeders and researchers who fear that utility patents on commercial cultivars will reach back to parent breeding lines and even unimproved germplasm” (Stiles, 1989, p. 40).

Other relevant problem relates to the eventual collision of rights that may take place, for instance, when a given patented trait (e.g. herbicide resistance) is later on found in nature and can

be incorporated in plants by using conventional breeding methods<sup>34</sup>. There is no clear legal interface in this case between patent holders and breeders' rights. Another problem would arise out if a patented "engineered" gene is introduced in a protected variety; neither the patentee nor the breeder would, in principle, have the right to use the property of the other<sup>35</sup>. Finally, just to mention a few hypothesis, if a (non essentially biological) process to obtain a variety is patented, under many patent laws the patent rights will extend to the products directly obtained by said process<sup>36</sup>, therefore indirectly making varieties protectable in this way.

#### **2.2.4 Disclosure and deposit**

One of the potential limitations to the patentability of living matter is the difficulty of describing it so as to meet the disclosure and reproducibility requirements of the patent system<sup>37</sup>. Disclosure is one of the pillars of the patent system, since it ensures that in exchange for granting monopoly rights the society benefits from obtaining access to new knowledge.

The deposit of the materials related to a claimed invention has been the mechanism envisaged to overcome the virtual impossibility of describing biotechnological inventions<sup>38</sup>. Access to the deposited strains is intended to constitute a substitute for the written description, which is published within a certain period after the date of application (in Europe, applications should be published after 18 months from filing) or the granting of the patent (such as in United States).

The Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure (1977), as revised in 1980, provides an international framework whereunder member States recognize for their own patent procedures deposits of samples of microorganisms made in an "International Depository Authority" (IDA) established in another member State.

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34 In accordance with one opinion, in this case a breeder can use traditional breeding techniques to include the gene in a cultivar without infringing the patent (Barton, 1993, p. 15).

35 The World Intellectual Property Organization (WIPO) Suggested Solutions recommended in this respect the following:

"Where the holder of a plant variety right for a variety that represents a significant technical advance over a patented invention in the relevant area wants to carry out an activity concerning the said new plant variety which is within the scope of protection of the said patent, he shall have a right to obtain a license under the said patent in order to carry out such activity, subject to the payment of a reasonable remuneration" (WIPO, 1988).

36 This is the principle adopted by the TRIPs Agreement described below (article 28.b).

37 Patent laws generally require that the invention be described in a manner that would allow its actual implementation by a person with an average knowledge in the respective field. Some laws (e.g. U.S) also require the disclosure of the "best method" known by the applicant. This latter requirement is optional under the TRIPs Agreement.

38 The deposit system was made available in the United States and several European countries since the 1950's.

Three issues are of particular importance with regard to the access to deposited materials in the context of the Budapest Treaty. The first issue relates to the concept of microorganism. WIPO - the administrative body of the Treaty - has interpreted that the concept of “microorganism” is not limited to the scientific notion, but embraces cells and sub-cellular parts (WIPO, 1988). This opens the possibility of depositing plant genetic resources, among other materials.

Second, the Budapest Treaty only determines the conditions for deposit and maintenance of strains, but does not empower the IDAs to check whether the claimed microorganism strictly corresponds to the deposited material (Assanti, 1983). The remedy for lack of correspondence would be provided by the cancellation of the patent, but the relevant material would remain inaccessible to third parties. Differences between the material claimed and that effectively deposited may give rise to abusive practices<sup>39</sup>. There is no guarantee that the deposited material is actually useful for experimental purposes or that it has not changed by mutation after deposit.

Third, the Treaty leaves to national legislations the crucial issue of conditions to access to the deposited samples. It is a matter of national laws, therefore, to determine when and under which circumstances samples may be obtained. Rule 11.3 (a) of the Regulations of the Treaty is based on the assumption that access to the sample will only be granted after publication of the relevant application.

Legal systems considerably vary on this topic. Under U.S. law access can only take place after the granting of the patent. In any case, any commercial use of the sample will amount to an infringement in the United States. Only experimental uses would be allowed. Under European law, in general samples may be obtained after publication of the application (before the patent has been granted), but through an independent expert and for experimental purposes only.

Until the end of 1990 IDAs had received 15.265 deposits, 51% of which in the IDAs established in the United States<sup>40</sup>. Until the same date only 256 samples (1,6% of the total) had been furnished to third parties under Rule 11.3 of the Regulations of the Budapest Treaty<sup>41</sup>.

Out of 26 IDAs existing as of January 1994, only one has been established in a developing country (South Korea). The Treaty has 29 members, including four developing countries<sup>42</sup>.

## **2.3. Protection via breeders' rights.**

### **a) Patents versus breeders' rights**

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39 See, for instance, the case submitted to the U.S. Federal Trade Commission with the respect to the antibiotics aureomycin (OTA, 1981, p. 247).

40 They are the American Type Culture Collection and the Agricultural Research Service Culture Collection.

41 Data based on statistics contained in WIPO, 1992.

42 Cuba, Trinidad and Tobago, South Korea and Philippines.

Breeders' rights protect plant varieties, which are new, distinct, uniform and stable. Like in the case of patents, breeders' rights do not give ownership of products, but the right to exclude non-authorized persons from using and multiplying propagating materials of protected varieties.

Many features differentiate patents from breeders' rights<sup>43</sup>. One of the main differences relate to the subject matter of protection. Breeders' rights apply to a specific variety which must physically exist, while patents refer to inventions which need not to be realized for obtaining protection.

Another important difference is that the breeder's rights system generally allows farmers to re-use in their own exploitations the seeds they have obtained<sup>44</sup>, a possibility that patents would exclude<sup>45</sup>.

In addition, under such systems protected varieties may be used for further breeding ("breeders' exemption), without the authorization of the title-holder. This is not possible, in principle, under patent law since the "experimental use exception" generally allows research with non commercial purposes only. The lack of a an exemption of this type is seen as one of the main negative implications of patenting in the field of plants, since it limits the free exchange of germplasm which is the driving force in plant improvement (see sub-section g. ii below)

## **b)The UPOV Convention**

Breeders' rights have been adopted by a relatively limited number of countries, mostly industrialized countries (see table 2<sup>46</sup>). Though only a few developing countries have implemented this system<sup>47</sup> and no one has yet become member to the UPOV Convention<sup>48</sup>, this situation is likely to substantially change with the implementation of the TRIPs Agreement. Many developing countries may be expected to adopt a *sui generis* regime for the protection of plant varieties, rather than patents.

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43 For a more detailed analysis, see Correa (1990).

44 The scope of this exception varies in different national laws. In the United States, for instance, it has been broadly admitted when the "primary farming occupation is the growing of crops for sale for other than reproductive proposes". Farmers have qualified for this exemption if 51% of their sales was not sold as seed for reproductive proposes (Jondle, 1989, p. 7). Proposals to reduce the scope of this exemption have been submitted to U.S. Congress.

45 Since living organisms are self-replicating, the sale of a patented organism is at the same time the sale of the means by which the organism can be replicated. Patent rights are deemed in this case to extend to the descendants of the protected organism.

46 This table is based on Greengrass, 1993, p. 47.

47 Draft laws are under consideration in India and Brazil.

48 Argentina and Uruguay have formally initiated the process to accede to the Convention. Mexico is obliged, under NAFTA, to join UPOV either under the 1978 or 1991 Act.

TABLE 2			
Countries which protect plant varieties with breeders' rights systems, as of January 1994			
UPOV members	UPOV non-member states		
	Laws in accordance with UPOV	Laws substantively in accordance with UPOV	Hybrid system of laws
Australia Belgium Canada Czech Republic Denmark Finland France Germany Hungary Ireland Israel Italy Japan Netherlands New Zealand Poland Slovakia South Africa Spain Sweden Switzerland United Kingdom USA	Argentina Austria Norway Portugal Uruguay Andean Group	Chile Kenya Zimbabwe	Mexico Republic of Korea Rumania

As shown by Table 2 some countries have adopted a "hybrid" regime of protection which does not substantially follow the UPOV system. As discussed below, the TRIPs Agreement does not necessarily implies an harmonization of national legislations in this area.

In response to the demands for strengthening the minimum standards of protection provided for under the UPOV Convention and, in particular, for eliminating the prohibition of a cumulative protection with patent rights, a Diplomatic Conference was convened on 4 to 19 March 1991. The revised Convention reflects to a large extent the wishes of large industrial R&D-based companies working in modern biotechnology. Among the main changes introduced by the 1991 Conference<sup>49</sup>,

49 The following analysis is based on Correa (1992).

it should be noted the expansion of the acts subject to the breeder's authorization in respect of the propagating material of the protected variety. They do not only include production, offering for sale and marketing, but also reproduction (multiplication), conditioning for the purpose of propagation, exporting, importing and stocking for the just mentioned purposes. This new drafting responds to the industry claims for a protection more similar to that conferred under the patent system.

The extension referred to in principle would exclude the 'farmer's privilege'. However, the member countries have the option to restrict the breeder's rights 'in order to permit farmers to use for propagating purposes, on their own holdings, the product of the harvest which they have obtained by planting on their own holdings' (Article 15 (2)). The explicit recognition of that exemption (albeit optional) was not in the previous Acts of the Convention. However, it is to be applied 'within reasonable limits and subject to the safeguarding of the legitimate interests of the breeder'. The net result is, on the one side, that one member State may allow free use of farm-saved seed while others may decide to bar it. On the other, even in the former countries the right-holder may prevent such a use on the grounds that its 'legitimate interests' will be prejudiced. The formalization of the 'farmer's privilege' in the text of the Convention, in short, means that said 'privilege' is not designed to give blanket rights to farmers but rather that member countries may establish exclusions to allow the farmer's privilege. Along this line, the Diplomatic Conference that adopted the 1991 revision indicated that Article 15 (2) should not be interpreted as extending the 'privilege' to sectors of agricultural or horticultural production where it is not 'a common practice'<sup>50</sup>.

Another important innovation of the new text is that the list of acts subject to the breeder's authorization also applies in respect to 'harvest material, including entire plants and parts of plants...unless the breeder has had reasonable opportunity to exercise his right in relation to the ...propagating material' (Article 14 (2)). Under this provision, for example, a breeder holding rights on a cereals variety could collect royalties on grain produced from his variety, except if he could have or actually had collected them on the seed itself. The revised Convention also prescribes that any member country 'may' extend the breeder's rights to the acts referred to end-products, when the breeder had no reasonable opportunity to exercise his right in relation to the harvested material.

An almost entirely new concept is introduced by the revised text in connection with 'essentially derived varieties', in order to prevent the protection of varieties that only present 'cosmetic' changes with respect to pre-existing varieties. In this regard, the revised Convention may contribute to dissipating some of the breeders' fears on the eventual impact of the patenting of genes that may be incorporated in their protected varieties.

The new provisions do not affect the 'research exemption' (usually known as 'breeders' privilege). This exemption allows the utilization of a protected variety as an initial source of variation for creating or marketing other varieties, that may be the subject-matter of a separate and independent protection.

Last, but not least, a fundamental point is the solution given to the critical problem of accumulation of breeder's rights and patents. Article 2 of the 1978 text requires that a State should

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50 It should be noted that the UPOV Convention contain minimum standards of protection and, hence, any member country may decide to provide higher protection than that resulting from the Convention rules.

opt to grant the special protection or a patent for a given botanical genus or species. The new Article 2 of UPOV 1991 does not exclude double protection<sup>51</sup>.

Developing countries may adhere to the 1978 Act until 31 December 1995, while other countries could only do it until 31 December 1993.

## **2.4 The TRIPs<sup>52</sup> Agreement**

### **2.4.1 General**

The TRIPs Agreement contains minimum standards for the protection of almost all areas of intellectual property to be observed by all members to GATT. Such standards need to be implemented by national laws. Countries failing to respect the agreed levels of protection may be subjected to a dispute settlement procedure within the World Trade Organization and, eventually, be imposed trade sanctions in other areas (cross-retaliations)<sup>53</sup>.

The TRIPs Agreement is the most comprehensive international instrument on intellectual property ever negotiated and adopted. The provisions contained in the Agreement constitute minimum standards, and hence Members can not be obliged to provide a “more extensive” protection. This is particularly important in view of the application of unilateral retaliations, such as under Section 301 of the Trade Act of United States. With the approval of the TRIPs Agreement, any controversy should be subject to a multilateral procedure of dispute settlement, and only after the completion of the dispute settlement process other actions may be adopted<sup>54</sup>.

The “method of implementing” the TRIPs provisions can be freely determined within the “own legal system and practice” of each country. There are considerable differences between legal systems, particularly those based on anglo-american and continental European law. These differences are noticeable, for instance, in the field of copyright and neighbouring rights, trademarks and trade secrets protection. Other differences may arise out from various levels of economic and technological development. Thus, developing countries have usually been more concerned about the availability of compulsory licenses on granted patents than developed countries.

The areas that, for the purposes of TRIPs, constitute “intellectual property rights” include copyright and “related rights”, trademarks, geographical indications, industrial designs, patents,

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51 See WIPO, IOM/2, 22 June 1989, at 11. In the case of conflict between a patent and a breeder’s right (for example due to the patenting of genetic material introduced into a protected variety) the parties may block themselves reciprocally, unless they agree to a scheme of cross-licensing.

52 Trade-Related Aspects of Intellectual Property Rights.

53 In exchange, and as a result of the adoption of the TRIPs Agreement, it should be understood that unilateral retaliations by countries will become objectionable under GATT rules.

54 President Clinton’s submission to U.S. Congress of the documents concerning the Uruguay Round Agreement of 15.12.93 states in this regard that “If Members of the Dispute Settlement Understanding (DSU) do not comply with their obligations at the end of the dispute settlement process, trade action under section 301 of the Trade Act of 1974 will be legitimized and there will be no risk of counter-retaliation”.

layout-designs (topographies) of integrated circuits and “undisclosed information”. Excluded from the scope of the Agreement are, therefore, breeders’ rights and utility models<sup>55</sup>. The exclusion of breeders’ rights indicates that the major actors in the negotiation of TRIPs - particularly the U.S.A - privileged a patent approach with regard to issues relating to innovation in the field of plants. It does not mean, in exchange, that breeders’ rights can not be considered a specific kind of intellectual property right (more precisely, of industrial property) since they convey all the characteristics of such rights.

The absence of rules in the TRIPs Agreement on breeders’ rights leaves the UPOV Convention as the single international instrument to provide for minimum standards of protection for plant varieties. Although various parts of said Agreement are relevant to the protection of plant genetic resources, only the pertinent texts on patent rights are dealt with here<sup>56</sup>

#### **2.4.2. Patents**

In the area of patent rights, TRIPs contains a number of important provisions. According to article 27.3 b) parties may exclude from patentability:

“plants and animals other than microorganisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof. This provision shall be reviewed four years after the entry into force of the WTO Agreement”.

This exception reflects the outstanding differences, even among industrialized countries, on the patenting of plants and animals. The EEC proposals in GATT aimed at maintaining the present position of European countries which are members to the European Patent Convention, a position so far confirmed by the still under discussion draft Directive on patents relating to biotechnology.

Various elements of article 27.3.b) need to be considered. First, unlike European law and other legislations that followed the same approach, said article refers to “plants and animals” and not to certain classification thereof (“varieties”, “races” or “species”)<sup>57</sup>. In the absence of any distinction - and in the light also of the second sentence of the same article that introduces an exception for one particular classification (“plant varieties”) - the exclusion is to be interpreted in broad terms inclusive of animal and plants as such, animal races and animal and plant species.

Second, the reference to “essentially biological processes” is limited by the exclusion of “non-biological and microbiological” processes. The concept of microbiological processes as an

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55 The utility models or “petty patents” protect minor innovations, mainly in the mechanical field. They have been recognized in many developed countries (Spain, Germany, Japan, etc) and are deemed to be of particular importance for developing countries.

56 For geographical indications (appellations of origin) and trade secrets, see section 3.1 below.

57 The distinction is important. Thus, the prohibition to patent a “variety” does not prevent in European countries to patent a plant as such. The acceptance of a patent application on the “Harvard mouse” by the European patent Office was, similarly, based on the judgment that it is not a “race” but a specifically altered animal which is patented.

exception to the exception is present in the European legislation and in the laws of various other countries. Its aim in the TRIPs context is to limit the exclusion of patentability to traditional breeding methods, while preserving the possibility to obtain protection, for instance, on developments based on cell manipulation or, with the advances in biotechnology, the transfer of genes. Under the commented text, processes employing microorganisms (such as fermentation) are also patentable, in accordance with current practice in most countries.

More complex and new is the concept of “non-biological process”. How a plant or an animal can be produced by a process which is not totally or in part biological? The source and grounds of this text are untraceable. It will probably create more problems than it may solve.

Third, and as an exception to the general authorized exclusion, Members must provide protection for “plant varieties” either by patents or by “an effective *sui generis* system or by a combination or both”. This obligation is another important basis for the expansion of the scope of intellectual property in a field that most developing countries keep as a part of the “public domain” till now. Although there is flexibility as regards to the form of protection, the fact is that all GATT member countries will be bound to protect plant varieties. The flexibility is here, again, a reflection of the lack of consensus among the industrialized countries themselves. While in the United States and in Japan a plant variety may be patentable, this is not the case in Europe, as discussed above. The reference to a “*sui generis* system” suggests the breeder’s rights regime. However, the possibility is open to combine the patent system with the breeders’ rights regime, or to develop other “*sui generis*” form of protection. It is unclear, indeed, why in an instrument aimed at establishing universal standards, the issue of the form of protection of plant varieties has not been settled in a more straightforward way, like in other matters of equal or similar importance<sup>58</sup>. In any case, considerable freedom has been left for national legislations to design the system of protection in this area.

Fourth, article 27.3.b) is the single provision in the whole TRIPs Agreement which is specifically made subject to an early revision - four years after the entry into force of the Agreement. This period is even shorter than the transitional period contemplated for developing countries (article 65). This solution suggests how difficult a compromise on the biotechnology-related issues has been and the need for a deeper examination of the matter.

Two other provisions of the TRIPs Agreement should be mentioned here. On the one side - as indicated above - protection of a process is extended to the products directly made with said process (article 28 1. b). On the other, in civil proceedings relating to process patents, the reversal of the burden of proof is established (article 34). This principle may have a substantial impact in the biotechnology field, given the importance of process patents and the often broad claims admitted in this field.

### **2.4.3 Implementation of the TRIPs Agreement**

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58 Neither the UPOV convention is mentioned at all in the TRIPs draft text nor breeders rights are considered a form of “intellectual property” under the Agreement. Another forgotten modality of protection are the utility models recognised in many developed and developing countries to protect “minor” inventions.

Intellectual property rights, like other rights, may be framed by national legislation with distinct features, to the extent that it is not limited by obligations emerging from international conventions. Though the Paris Convention, UPOV and, particularly, TRIPs, impose a number of minimum standards and limitations, some room exists in various areas to define the scope of acts subject to exclusive rights and other aspects of the systems of protection.

Different modalities of implementing the systems of protection will certainly lead to different effects, at least with regard to some activities and interests concerned. This particularly applies in three areas, as discussed below.

### **i) Patents and “*sui generis*” regime**

Countries may, under TRIPs, opt to protect plant varieties either by means of patents or of a “*sui generis* regime”. They can also combine both systems and accumulate patents and breeders’ rights protection. While UPOV Convention, as revised in 1978, prohibited the accumulation of breeders’ rights and patents, this restriction has been eliminated from UPOV as revised in 1991<sup>59</sup>.

Since the protection of plant varieties on the basis of patents may have important implications for the access to genetic material for development of new materials, as well as for the on-farm use of seeds, it is likely that many developing countries that need to introduce protection consider as a first option a *sui generis* regime based on the concept of breeders’ rights.

The TRIPs Agreement does not oblige, like in the case of other conventions and treaties<sup>60</sup>, to follow the standards set forth by the UPOV Convention. If this is the case, however, developing countries may opt to accede to the UPOV Convention, 1978 Act, until the end of 1995. Thereafter, the only option would be to become a member to the 1991 Act.

Another possibility is to develop a *sui generis* regime of protection on new grounds. To the extent that it provides an “effective” protection and that it complies with binding general principles (e.g. national treatment), such an approach would in principle be compatible with the TRIPs Agreement<sup>61</sup>.

### **ii) Materials existing in nature**

It is well accepted under patent law that “discoveries”, as opposed to “inventions”, are not patentable. This principle may be applied in order to exclude the patentability of substances, including genetic materials, which already exist in nature. Countries may, thus, under TRIPs rules

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59 This implies that under UPOV 1991, member countries may, but need not, to grant both breeder’s rights and patents.

60 The Agreement requires parties to GATT (even those that are not members) to comply with the obligations established - with some exceptions - by the Paris, Berne and Rome Conventions, and by the Washington Treaty on integrated circuits. The latter has never entered into force.

61 It could, for instance, combine the concepts of breeders’ rights with the implementation of “farmers rights”, i.e., the recognition of a right to remuneration (collectively administered) to compensate farmers for their “informal” innovations and conservation of germplasm.

legitimately consider outside the scope of the concept of “invention”<sup>62</sup> any naturally occurring substance and process as well as isolated DNA sequences, even if transferred to different organisms<sup>63</sup>

### **iii) Non-voluntary licenses**

The granting of non-voluntary licenses<sup>64</sup> has been provided for in most legislations in the world, including the majority of industrialized countries. The TRIPs Agreement contains certain provisions that limit the modalities under which such licenses may be granted, but does not restrict the grounds for their concession.

Non-voluntary licenses may be granted, for instance, by reasons of public interest, public health or nutrition, anti-competitive practices, to ensure access to environmentally sound technologies, among others<sup>65</sup>.

## **2.4.4 Importance of intellectual property rights for plant innovations**

How important intellectual property protection for inventions is in the area of plants? As a general rule, it may be argued that the importance of legal protection is inversely related to the “technical” protection of a product or process, i.e., to the relative difficulty of imitating them due to barriers of access to the relevant knowledge or materials. The lowest the technical protection is, the highest will be the interest in obtaining a specific legal protection.

The degree of technical protection may be measured as the ratio between the time necessary to develop an innovation and the time necessary to imitate it. Imitation is more interesting (for the imitator) when the time to imitate is lower; the interest decreases as the time of imitation is closer to the time of development, except where some other economic or technological reasons justify imitation. A ratio time of imitation/time of innovation close to 1 favours innovation, while a ratio near to 0 favours imitation (Jullien, 1989, p. 35).

Three situations may be distinguished:

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62 This possibility is not banned by the TRIPs Agreement, which does not contain a definition of “invention”. The Mexican law excludes the patentability of all genetic materials. This has not prevented Mexico to adhere and be accepted as a member to NAFTA, which contains standards of protection even higher than TRIPs.

63 The “Suggested principles for a future CGIAR policy on intellectual property rights”, issued in October 1991, recommended that patents should never be sought by the Centres for “naturally occurring genes”.

64 A “non-voluntary” (or “compulsory”) license is an authorization conferred by the State to use an invention (generally against the payment of a royalty) without or against the consent of the title holder, if certain circumstances exist. Such licenses have typically been provided for to prevent abuses by title-holders.

65 See, for instance, UNEP Third revised draft convention on biological diversity, UNEP/BIO.Div./N5-INC3.2., 9 October 1991.

-the knowledge on the innovation may be recovered by access to the product and, hence, weak technical protection exists;

-said knowledge can only be partially recovered on the basis of the product;

-the knowledge is not embedded in the product and can not be recovered from it.

Table 3 summarizes the precedent scheme for a number of techniques and products in plant biotechnology. It indicates that, for instance, while the likelihood of imitation is high in the case of cellular fusion and transfer of genes, it is low in the case of in vitro multiplication or somoclonal variation.

Techniques	Embedded in products	Time imitation/ time innovation
Multiplication in vitro	NO	Near to 1
Somaclonal variation	NO	Near to 1
Haploidization	Partially	Undetermined (dependent upon required quality)
Cellular fusion	YES	Near to 0
Gene transfer	YES	Near to 0

*Source: Jullien, 1989, Table I.5*

Seeds carry on the genetic information that generate their agronomic and economic value. Their technical protection varies significantly, in accordance with the species and their forms of propagation. Thus, hybrid seeds is a well known example of high technical protection based on secret know how which is embedded but not easily accessible. On the other extreme are the self-pollinated species, since seeds obtained by cultivation may be re-utilized and used for further reproduction.

### **2.4.5 Implications**

As mentioned above, the implications of intellectual property on the access, use and development of plant genetic resources will be dependent on the type of protection which is implemented and on the extent of rights conferred under the selected form. Thus, the implications of breeders' rights is likely to vary in accordance with the extent of exemptions admitted, particularly with respect to the "farmers' privilege". In the case of patents, many factors are to be taken into account, including the availability of compulsory licenses, the scope of the exception for experimental use, the definition of invention, the type of claims accepted, etc.

The impact of patents, in particular, should be analyzed with respect to several issues<sup>66</sup>.

#### **a)Seed prices and concentration**

Patents create a legal monopoly that normally leads to price increases, as a logic consequence of the suppression of competition for a particular product/process. In particular, increased seed costs may be expected for open-pollinated crops where farm production of seeds is a common practice which would be banned by patent rights. The introduction of plant breeders' rights may also contribute to an increase of seed prices, but eventually limited by the less stringent conditions of protection. Concern about the impact on the agricultural sector in terms of vertical integration has also been expressed, since patent owners might tend to contract out the farming and impose a crop purchase requirement upon the farmer (Stiles, 1989, p. 43).

#### **b)Research and breeding programs**

Germplasm development is an essentially cooperative activity: "Most breeders feel that the knowledge they gain by observing products developed by others, and the possible use that they may be able to make of it in a future cycle of selection, outweigh the risk to them of someone else using material they have developed. Plant breeding is enough of an art so that practitioners feel confident of maintaining an edge over any competitor's use of their material. Coupled with breeders' desire to see the broadest possible use of the genetic base, this gives them a tendency to want to cooperate by exchanging genetic material. Each breeder knows that restricting access to samples of his or her own material will lead to similar treatment from colleagues" (Fraleigh, 1991, p. 3).

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<sup>66</sup> These issues are briefly presented below. Research on the impact of intellectual property is scarce, and would need to be substantially improved in order to address the major issues relevant in this area.

Many experts and breeder organizations have taken the view that the “experimental use” exception under patent law is too restrictive to allow continuous progress in breeding, and that it should be modified in order to meet the particular needs of this activity. Thus, ASTA took the position that “all improved plant germplasm offered for sale any place in the world is available for legitimate breeding purposes...” (Schapaugh, 1989, p. 20). Given the likely deleterious effect of patenting on future genetic progress (Plowman, p.39), it has been suggested “to develop a research exemption policy that maximizes and facilitates breeder access to germplasm worldwide” (CSSA, 1993, Policy recommendations of Workgroup D)<sup>67</sup>.

Patents may, in particular, limit research and development on the genetics of traits which are already patented, since all possible uses of such trait may fall under the patent claims.

In addition, the possibility of patenting research results made by universities and other public institutions may, in accordance with some views, affect the direction of research programs and reduce resources available for projects not aiming at a possible commercial outcome (Kline, 1989, p. 33). This is, however, a problem of public policies and of preserving the necessary balance between basic research and development.

### **c)Genetic diversity**

Patenting may negatively affect diversity, to the extent that certain lines of research (e.g. on some traits) may be discouraged or limited by existing patents, thus limiting the genetic diversity of the plants bred to express the trait. Further, patent rights are likely to interfere with exchange of materials among researchers, universities, private laboratories and industry. The implications of patenting plant genetic resources have been persuasively presented by Powelman (from the U.S. Agricultural Research Service - ARS - of the Department of Agriculture):

“An examination of 140 important rice accessions done recently indicates that their ancestry can all be traced to 22 introductions in the southern rice belt and 23 introductions in the western rice belt. What if the genes of several of these ancestral lines had been unavailable or financially out of reach of the breeders? If you eliminated parents that were themselves released varieties, would we have made such progress? And how expensive would the seed be if growers were paying a royalty for each ancestor?”

Remember the semidwarf wheat varieties? What if Dr. Vogel had chosen, instead of widely distributing his first variety and its sister lines, to patent his material? Would there have been a Green Revolution in Wheat?

The Agricultural Research Service has recently signed off on the release of a new corn germplasm that carries unique resistance to fall armyworm. What would be the consequences were the Agricultural Research Service to patent this release? Would this resistance only be available to the highest bidder? I don’t believe that ARS, as a public agency, should operate in such a manner” (Plowman, 1989, p. 36).

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<sup>67</sup> The Mexican patent law (1991) provides an example of provision of an exception similar to the breeders’ exemption in the patent field. The exemption could also be applied for varieties developed and patented by public and quasi-public research entities (Plowman, 1993, p. 39).

In accordance with a similar view,

“If plant patenting seriously interferes with the flow of germplasm, the ultimate adverse impact may be much greater than incentive effects on research and revenues. The ARS wishes to assure that access to germplasm remains unrestricted between scientists, organizations, and nations” (Tallent, 1989, p. 50).

The extent to which the monopolization derived from patent protection conflicts with the principles and objectives of the FAO International Undertaking and of the Convention on Biological Diversity needs to be further analyzed in the context of a possible revision of said Undertaking. The existence of a conflict in this respect has already been noted (Stiles, 1989, p. 44), and more research on the subject should be encouraged.

#### **d) Foreign direct investments and technology transfer**

The recognition of intellectual property rights is often viewed, in a North-South perspective, as a means necessary to promote flows of foreign direct investments and of technologies to developing countries. Little may be said with respect to the likely impact of patenting of plants on those flows, since no empirical evidence is available. Previous analyses on the subject indicate that no conclusive argument can be made on the relationship between higher levels of protection and the nature and dimensions of such flows (Correa, 1993). They also indicate that it is not possible to assume that providing protection would automatically lead to more investments or technology transfers, but rather that technology owners may prefer to commercialize their inventions incorporated in goods, i.e. through trade.

### **3. “Informal” innovations**

#### **3.1 Protection of traditional knowledge of communities**

The contributions made by generations of farmers to the conservation of germplasm and the improvement of species, has been recognized by the international community, particularly under the International Undertaking on Plant Genetic Resources and the Convention on Biological Diversity (article 8.j). Growing recognition also exists on the contributions made by indigenous and local communities to the knowledge on plant uses, particularly for therapeutical purposes.

The concept of “informal innovation system” was first suggested at a Seminar convened by the African Academy of Agricultural Sciences in 1989. Based on this concept, the notion of “informal innovation” gained growing acceptance, and was incorporated in Chapter 16 of Agenda 21 in connection with the safe management of new biotechnologies<sup>68</sup>.

The appropriateness of this shift in the concept from the “system” to the “innovation” as such is questionable, since most innovations are in fact “informal”, for they are the result of empirical, cumulative, knowledge neither codified nor formalized in a patent-like way. A considerable portion

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68 See CPGR (1992).

of the knowledge and technologies in use, even in high-technology areas, are of a “tacit” nature (David, 1992), eventually protected under the loose regime of trade secrets law.

Whatever the adequate terminology is, the question is how to reward those communities that have developed and preserved valuable knowledge and preserved germplasm for generations. Proposals have included an extension of intellectual property rights, as well as the recognition of “cultural” rights. The International Undertaking has adopted the concept of “farmers’ rights” to be implemented through an international fund.

The development of methods of compensating the contributions of indigenous and local communities requires, first, the identification of the categories of knowledge/materials of actual or potential value for the conservation and use of plant genetic materials which may constitute the subject matter of conferred rights. These categories may include information on specific materials and knowledge such as information on:

- the use of plants;
- the preparation, processing, and storage of useful species;
- formulations involving plants;
- individual species (planting methods, caring for, selection criteria, etcetera);
- ecosystem conservation.

Second, the types of rights that may be conferred should be examined, in accordance with the nature of the knowledge involved. One hypothesis that should be disregarded from the outset is the extension of patent-like rights to knowledge which does not comply with the novelty and inventive-step requirements of patent law. A weakening of such requirements could only be in the advantage of those that today possess the greatest resources to undertake innovatory activities<sup>69</sup>, as well as to make use of any mechanism of protection established by law.

Third, it should be noted that a “traditional” knowledge does not necessarily mean a frozen, immutable, knowledge, but it includes usages that are adapted and evolve over time. Tradition, in this sense, “is rather the permanent addition of present times to past knowledges” (Bérard y Marchenay, 1993).

If the scope of patentability (or appropriation through similar titles) is expanded, knowledge that today is in the “public domain” would become subject to exclusive rights. The advantages of a further monopolization of knowledge are less from evident. On the contrary, it would seem desirable to promote a system that, while reasonably compensating for the efforts made, does favour the diffusion of useful knowledge.

Another problem not to be overlooked relates to the enforcement of eventually conferred exclusive rights. A theoretically appropriate means of protection may be useless if potential interested parties have no effective means to get recognition of their rights (for instance, if registration and compliance with certain legal formalities are required), or once recognized, they are unable to effectively enforce them against infringers, usually a complex and costly task. In addition,

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69 Developing countries - including China - only account for about 6% of the world expenditures on research and development.

the cost of administration of the system would have to be assessed in order to establish, in particular, whether they would offset its expected benefits.

In considering possible developments in the field of intellectual property, attention should also be paid to the current availability in gene banks, free of charge, of about 3 million and a half accessions of plant genetic resources for food and agriculture (perhaps 50% of which are unique samples) (Vellvé, 1994, p. 7). If these resources are left outside - as it would seem likely - the significance of an eventual new system of protection based on exclusive rights, if feasible at all, will be greatly reduced, since breeders and scientists will continue to have unrestricted access to an enormous source of diversity stored in *ex situ* collections.

Based on present institutions in the field of intellectual and cultural rights, possible forms of direct and indirect protection or compensation for traditional farmers include the following:

### **i) Trade secrets**

Some valuable knowledge may be preserved as secret, particularly in cases of the application of plants for therapeutical purposes. Holders of this knowledge may well be protected under unfair competition rules, which do not require previous registration or other formalities.

Trade secrets protection, unlike patents, does not confer an exclusive right, but the right to prevent the acquisition and use by third parties of the protected information in a manner contrary to honest commercial practices.

Any secret information of commercial value may be protected under trade secrets (see section 7 of the TRIPs Agreement), but most legislations require, as a condition for protection, that the person in control of the information adopt the steps necessary, under the relevant circumstances, to keep the information confidential. In other words, there should be deliberate acts aimed at protecting, as secret, the relevant information.

### **ii) Appellations of origin**

Geographical indication is basically a mark used in connection with goods or services in order to indicate their geographical origin. Three types of geographical indications may be distinguished: (a) qualified indications of origin<sup>70</sup> having a particular descriptive meaning due to particular characteristics of the products essentially attributable to a country, region or locality. This indications are also known as “appellations of origin”<sup>71</sup>; (b) simple, quality-neutral geographical indications of source, i.e, those where there is no direct linkage between certain characteristics of the products and their geographical origin; (c) indirect geographical indications of source, that is, indications that are associated by the public with a certain geographical region<sup>72</sup>.

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70 The TRIPs Agreement only obliges Member countries to protect this type of indications.

71 Some typical examples include Champagne, Bordeaux, Pilsen, Havana.

72 This is the case, for instance, of “Mozart-Kugeln” which is associated by the consumer with Austria, and of “Ouzo” and “Grappa”, associated to Greece and Italy, respectively.

This modality of protection might be applied to centres of diversity of certain crops (CPGR, 1992) in a way similar to their application to wines and spirits. It may constitute a suitable mechanism to ensure the value of agricultural products and to contribute to the prosperity of rural areas.

The protection conferred under these titles may be exercised through associations representing the producers of the concerned region or area. It should be noted, however, that the appellations of origin do not protect a specific technology or knowledge as such, but only prevents the false use of the geographical indication.

### **iii) Cultural property**

It has also been suggested (Reid et al, 1993), that indigenous peoples' traditional knowledge may be protected as a cultural property under the terms of the Convention on the Means of Prohibiting the Illicit Import, Export and Transfer of Ownership of Cultural Property, administered by UNESCO. Each party to the Convention may designate the categories of property to be considered "cultural property", which may include "rare collections and specimens of fauna (and flora)". Property to be protected may have been created by individuals or collectively.

### **iv) Expressions of folklore**

The UNESCO/WIPO Model Provisions for National Laws for the Protection of Expressions of Folklore against Illicit Exploitation and other Prejudicial Actions, have often been mentioned as a possible framework for the protection of traditional knowledge (see, for instance, Posey, 1993). The Model Provisions attribute rights not only to individuals, but also to communities, and allow the protection of an ongoing or evolutionary creations<sup>73</sup>.

This type of protection belongs to the area of copyright, where only the expression of a work and not the underlying ideas are protectable. This certainly limits its eventual usefulness as a means of protecting and compensating methods or knowledge of a functional character.

## **3.2 Remuneration rights**

An alternative for recognition of farmers contributions which might be explored consists of a system whereby a right to remuneration (not associated with the exercise of an exclusive right) is ensured to compensate the contributions made by communities. Some situations in the intellectual property field have been addressed by systems of that type. This is the case, for instance, of the public lending right, that is, the right to a remuneration (that in certain countries is directly made by the State) for the lending of books from public libraries. The respective amount is distributed among authors in accordance with certain criteria, such as the number of books in the libraries' stocks.

Another example is the blank tape royalty established in many European countries, which applies on tapes suited for private use. This royalty is intended to compensate authors for the

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73 Only Bolivia and Morocco have apparently implemented rules in the framework of the Model Provisions.

copying of audio and video tapes without the authors' consent, and is premised on the impossibility of actually controlling private copying.

In many other areas of copyright and neighbouring rights, difficulties to exercise exclusive rights have led to the establishment of remuneration schemes with collective administration organizations (WIPO, 1990). These organizations collect the license fees and other remuneration, and distribute them among the authors concerned.

The collective administration of rights is also emerging in the area of seeds. In the case of Argentina, for instance, the Asociación para la Protección de las Obtenciones Vegetales (ARPOV), a private association of seed producers, collects royalties for the use of seeds in representation of the individual firms. The system has significantly improved the compliance with the legislation on breeders' rights.

### **3.3 Farmers' rights**

The implementation of "farmers' rights" (as defined by the International Undertaking) may be considered in the framework of the above discussion.

Such rights have not been conceived by FAO Conference as an exclusive right, but as a right to obtain a compensation<sup>74</sup>. As mentioned, this is perfectly in line with many situations in the copyright law, where the exercise of exclusive rights is impossible or extremely difficult.

On the other side, reference has been made both to cases where rights are attributed not to individuals but to a collective entity, and cases in which the administration of the remuneration is administered by a collective organization.

Farmers' rights could, within this framework, be implemented either through a multilateral agreement or national legislation, provided that a proper identification of the obligated parties and of the nature of the right is made. The rights would not accrue to the farmers themselves, but to the governments or other organizations representing the farmers' interests. At the national level a royalty could be charged on traded seed and the collected funds be distributed to and administered by collective organizations representing farmers' interests.

An example of implementation of farmers' rights at the national level is contained in a draft law on plant varieties protection under consideration in India<sup>75</sup>. In accordance with this proposal, a

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74 Given the non-binding nature of the International Undertaking, there is not in legal terms a "right" and a related "obligation", but only the acceptance of the notion that such a right should be recognized and implemented by the international community.

75 The proposed legislation defines farmers' rights as follows:

"The farmers rights for the purpose of this Act mean the rights arising from the past, present and expected future contributions of farmers in ensuring conservation, improvement and availability of plant genetic resources, particularly in the centres of origin or diversity through a continuous engagement in an

“National Community Gene Fund” would be established. Its funds would be utilized in trust of Indian farmers for collecting, evaluating, upgrading, conserving and utilizing genetic variability. One of the resources of the Fund will be based on a percentage of the total sales of protected varieties. The law would, through this mechanism, implement the sharing of benefits in the gains accruing from the commercial exploitation of germplasm.

The implementation of farmers’ rights at the national level might contribute to compensate the farmers of a given country for their contributions. The impact of the system would be partially dependent on demand elasticity and the extent to which prices of seeds and of final products are affected. Only in this latter case the resulting increase would be covered by the community at large. National laws implementing farmers’ rights represent a step forward, but does not solve the problem of compensating farmers at the global level, given the global nature of the values of germplasm farmers provide.

At the international level, the implementation of farmers’ rights would require further progress in the constitution of an international fund in the framework of the FAO Global System, including the States and other parties’ contributions. Clearly enough, there will be in reality no “right” until the corresponding “obligation” is not defined and legally established.

#### **4. Conclusions**

The principle of sovereign rights over plant genetic resources has been strongly endorsed by the international agreements briefly reviewed above, and is increasingly introduced in an explicit manner in national legislations. Although such rights are limited by the right of access by other countries, States have retained the freedom to determine the conditions whereunder such an access may take place.

States also have freedom to define the nature of the rights (proprietary or not) that may be claimed in respect of plant genetic resources as physical entities residing in their territories. Options include considering them as a public or private property. The implications of these different options should be further researched. The constitutional and law rules described above seem to indicate that preference is given to the concept of public property on wild resources, which are deemed a part of the “national patrimony”.

National law on the physical property of plant genetic resources has an overriding effect on the legal status of all germplasm residing in the territory of the respective State, including *ex situ* collections, except in cases where international agreements have been established.

The genetic information may be appropriated, according to present legislative trends, via intellectual property rights, for a limited period. Particularly relevant for plant genetic resources are breeders’ rights and patents. In industrialized countries, the latter tend to be applied to plants, cells and sub-cellular components (including genes), though differences emerge with respect to the protection of plant varieties.

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on-farm evolution of variations within varieties. For their above said contributions, the farmers are entitled to full benefits and support in the continuation of their contribution” (article 22.ii).

The patenting of plants and their components have raised a number of issues, particularly with respect to the access to deposits and the scope of claims. Patent law, unlike breeders' rights systems, would not allow for exceptions similar to the farmers' and breeders' exemptions. The impact of the lack of a breeders' exemption on the exchange of germplasm and on breeding activities has created considerable concern.

International rules on intellectual property adopted under the TRIPs Agreement, define a number of minimum standards of protection to be observed by all GATT member countries, particularly with respect to geographical indications and patents. Such standards will require the protection of plant varieties, either by patents, a *sui generis* regime or a combination of both, but allows countries to exclude the patentability of plants and of the essentially biological processes for their obtention. Likewise, The patentability of genes and other biological substances existing in nature, accepted under the legislation and practice of some countries, is not determined by the TRIPs standards and, therefore, can also be excluded by national law.

The issue of protection of traditional knowledge of local and indigenous communities may be addressed in the framework of some chapters of intellectual property or cultural rights. Although further clarification is still required, it is in governments' hands to define and establish the appropriate legislation<sup>76</sup>, which may be based on the concept of a "remuneration right" rather than attempting the creation of exclusive rights.

Like any other right, the legal existence of farmers' rights need the identification of subject matter, scope, title-holders and obligated parties. Such rights might be sanctioned at the multilateral level or at the national level (or both). Considerable consensus has emerged in recent years with regard to most of the elements necessary to constitute such rights at the international, conceived as a right to a remuneration. A number of issues, however, need further clarification and the development of the appropriate institutional mechanisms.

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76 As mentioned in the text, intellectual property legislation, as other forms of property, must be established by law. They are not naturally "inherent" to any good.

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