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THE CURRENT LAW OF PLANT GENETIC RESOURCES AND TRADITIONAL KNOWLEDGE

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2.1 Introduction

This chapter seeks to lay out the main legal foundations in existing international law for the protection of plant genetic resources (PGR) and traditional knowledge (TK). It is, primarily, an exercise of stocktaking, of providing a survey and of identifying issues to be dealt with in successive chapters.

The chapter first introduces the general principles of international law, which, today, are enshrined by the doctrine of permanent sovereignty over natural resources. While there was a trend to address the heritage of biological diversity in terms of a common public good and ascribe it to the limited domain of common heritage, it is well established, since the 1992 Rio Conference and subsequent instruments, that the matter does pertain to national sovereignty and therefore national regulation within the bounds of international law. A survey of international agreements, in particular the Convention on Biodiversity (CBD), affirms this view. Equally, a survey of agreements which seek to provide an open, multilateral international system within the International Undertaking on Plant Genetic Resources (IUPGR) (International Undertaking; IU) and the new International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA), administered by the Food and Agriculture Organization (FAO), confirm the point by way of introducing mutually granted concessions of unimpaired facilitated access to plant genetic resources. Similarly, the efforts within the Consultative Group on International Agricultural Research (CGIAR) in supporting an open system confirm the overall principle. This chapter then provides a short survey of World Trade Organization (WTO) law and seeks to identify its main implications for PGR and TK. Given its comprehensive and complex structure, the Agreement on Trade-related Aspects of Intellectual Property Rights (TRIPS Agreement) will be examined in detail in subsequent chapters of this book. The same is true for other instruments addressing property rights, in particular the *Union internationale pour la protection des obtentions vegetales* (UPOV)

Convention and the ITPGRFA. Finally the survey addresses pertinent national legislation by way of example. A short description of the European and US intellectual property rights (IPR) system provides the necessary background, as a brief introduction to access legislation currently existing or partly enacted in developing countries, under the doctrine of permanent sovereignty over natural resources.

At this stage, it is already clear that the problem of PGR and TK is formed by a host of different principles, rules and agreements, most of them administered by different international organizations and fora, and thus also by different national authorities and constituencies: from departments of the environment, to agriculture, to foreign trade, human rights, human health, plant and animal health, to intellectual property, competition, and perhaps additional ones. They all face the problem of policy coordination at home, and even more so at the international level. The system is still highly fragmented, organized in different chapters, often without much coordination or interaction between these. It will be one of the major goals to bring about structures in the field that allow meaningful interaction, cooperation and joint decision-making.

2.2 Permanent Sovereignty over Plant Genetic Resources[1]

State sovereignty remains the fundamental principle around which all inter-state relations are organized.[2] In effect, international law is based on the principle that all states are juridically equal and that there is no authority superior to states. One of the specific elements of state sovereignty concerns the control of the natural, biological and genetic resources found in areas under their jurisdiction.

The question of sovereignty over natural resources was the object of intense debate in the aftermath of decolonization. Newly independent states, after gaining political independence, sought to gain control over resources found under their jurisdiction, with a view to gaining control over the exploitation of economically valuable natural resources. The recognition of States' Permanent Sovereignty over Natural Resources was first formalized in a UN General Assembly Resolution.[3] This principle refers to the right of each state to freely exploit and develop its natural resources. It constitutes the basic principle for allocating rights and responsibilities in international law in this field. The principle of permanent sovereignty has since been reiterated in numerous treaties and other international documents. Its binding status in international law is unquestioned (Schrijver, 1997).

One of the attributes of sovereignty is that states can freely choose to restrict it by way of agreement. In the field of the environment, the scope of sovereign rights has slowly been circumscribed. In fact, one of the most generally recognized principles of customary international law in the field of the environment is Principle 21 of the Stockholm Declaration, which provides that states have

> 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.[4]

[1] Author: Philippe Cullet.

[2] UN Charter, San Francisco, 26 June 1945 and UN General Assembly Res. 2625 (XXV), Declaration on Principles of International Law Concerning Friendly Relations and Co-operation among States in Accordance with the Charter of the United Nations, 24 October 1970, reprinted in 9 ILM 1292 (1970).

[3] UN General Assembly Resolution 1803 (XVII), 14 December 1962, Permanent Sovereignty over Natural Resources, reprinted in 2 ILM 223 (1963).

[4] Declaration of the United Nations Conference on the Human Environment, Stockholm, 16 June 1972, reprinted in 11 ILM 1416 (1972).

This basic limitation on states' rights to use their territories and resources as they see fit was confirmed in the Rio Declaration.[5]

Further refinements have been added over time. Specific issues have given rise to special principles. In the case of biodiversity, states negotiating the CBD found a specific compromise. The convention 'reaffirms' states' sovereign rights over their biological resources but increases their responsibility to conserve and sustainably use the resources they control.[6] The responsibility that states have towards the international community is encapsulated in the principle of 'common concern'. Common concern implies that the sovereign rights that are recognized as belonging to states are tempered by the international community's interest in the conservation and sustainable use of a global good (Boyle, 1994). In other words, states retain control over their biological resources but have a duty to cooperate with other states in resolving issues of interest to the international community.

Apart from the special principle of 'common concern' devised for biological resources, distinct rules have also evolved in the case of genetic resources. The development of rules for the control of genetic resources has followed a different trend from biological and natural resources found under the jurisdiction of states. Plant genetic resources were traditionally seen as a common heritage of humankind.[7] The main implication of the common heritage status in the case of genetic resources was that there should be no restriction on availability and, consequently, appropriation under private right schemes was deemed inappropriate. This constituted the core principle of the 1983 International Undertaking. The notion of common heritage has progressively given way to appropriation under the guise of both private rights and sovereign rights. First, disagreements over common heritage status in the context of the International Undertaking have led states to adopt interpretations of the International Undertaking that could be accepted by all FAO member states. The 1989 resolutions maintained the principle of common heritage but intimated that both plant breeders' rights and farmers' rights were compatible with the principle of common heritage.[8] Secondly, the CBD recognized states' sovereign rights over both biological and genetic resources that fall under their jurisdiction. Since the principle of common heritage had by 1993 become redundant, it became necessary to renegotiate the International Undertaking to take into account the new trends towards appropriation and benefit sharing. The resulting ITPGRFA makes no mention of the principle of common heritage.

The regulation of genetic resources presents further difficulties. Given their nature, a state's control over its genetic resources is even more difficult to assert than control over biological resources. The rapid development of genetic engineering has led to calls for new rules to regulate access to genetic resources. The CBD specifically addresses this issue. Article 15 recognizes states' sovereign rights to regulate access to their genetic resources. However, it goes on to impose an obligation on states not to unduly restrict access by other parties. In other words, the CBD gives states the authority to ultimately determine con-

[5] Principle 2, Rio Declaration on Environment and Development, 14 June 1992, Rio de Janeiro, reprinted in 31 ILM 874 (1992).

[6] Preamble, Convention on Biological Diversity, Rio de Janeiro, 5 June 1992, reprinted in 31 ILM 818 (1992).

[7] The concept of common heritage was first developed in the context of the law of the sea concerning deep seabed resources. See, for example, UN General Assembly Res. 2749 (XXV), Declaration of Principles Governing the Seabed and the Ocean floor, and the Subsoil Thereof, Beyond the Limits of National Jurisdiction, 17 December 1970, GAOR 25th Session, Supp. 28 (A/8028).

[8] Res. 4/89, Agreed Interpretation of the International Undertaking, 29 November 1989, Report of the Conference of FAO, 25th Session, Rome 11–29 November 1989, Doc. C89/REP and Res. 5/89, Farmers' Rights, 29 November 1989, Report of the Conference of FAO, 25th Session, Rome 11–29 November 1989, Doc. C89/REP.

ditions for access to their resources but at the same time strongly encourages them not to simply deny access to other contracting parties. While states are asked to provide regulated access to their genetic resources, the CBD makes provision for two important factors. First, access must be subject to prior informed consent. Secondly, the benefits directly or indirectly derived from accessing genetic resources must be fairly shared. This ensures that while states are strongly encouraged to provide access to resources that are under their sovereignty, they also participate in the benefits arising from this limitation of their sovereign rights.

Finally, the special situation of genetic resources held in the gene banks of the Consultative Group on International Agricultural Research (CGIAR) should be mentioned. These accessions have, in most cases, been provided voluntarily by states party to these *ex situ* gene banks, on the understanding that all designated germplasm held by the various International Agricultural Research Centres (IARCs) would be freely accessible. The CGIAR has been under pressure to revise its intellectual property guidelines in recent years. The basic principle remains that the IARCs do not apply intellectual property protection to their designated germplasm and require recipients to observe the same conditions. They also refrain from asserting IPRs over the products of their research. An exception to this rule is made in case the assertion of IPRs facilitates technology transfer or otherwise protects developing countries' interests. The CGIAR also imposes the condition that any IPRs on the IARCs' output will be assigned to the Centre and not an individual. While the guiding principles on intellectual property generally seek to contain to an extent the monopoly elements of IPRs such as patents, plant breeders' rights are specifically welcomed (Consultative Group on International Agricultural Research, 1999). Recipients of germplasm can apply for plant breeders' rights as long as this does not prevent others from using the original materials in their own breeding programmes.

This brief review of the evolution of the concept of sovereignty in the specific field of biological and genetic resources can be summarized as follows. First, at least since the 1960s, the principle that states have sovereign rights over their natural and biological resources has been reiterated on numerous occasions. Secondly, genetic resources that used to be considered a common heritage of humankind are now firmly included in the same category as biological resources. Thirdly, the relative importance of the notion of sovereignty should not be overestimated, since there has been a parallel trend towards much stronger private property rights over biological and genetic resources, in particular IPRs. Overall, the main trend over the past few decades has been towards the appropriation of economically valuable resources either through sovereign or private property rights.

2.3 International Agreements and Institutions

A number of international agreements constitute the law concerning PGR and TK at the international level. This section highlights some of the most significant treaties and institutions dealing with the management of biological and genetic resources, IPRs and issues surrounding the conservation and use of TK.

2.3.1 The Convention on Biological Diversity[9]

The CBD, even more than most environmental treaties, is the result of the progressive development of international environmental law since the early 1970s. Since the 1972 Stockholm Conference, states have signed various regional and international agreements designed to deal with various environmental issues, from

[9] Author: Philippe Cullet, with the help of Danuta Szymura Berglas.

the protection of specific species, habitats or ecosystems, to treaties dealing with the use and exploitation of environmental resources, as well as treaties addressing some of the consequences of industrial activity, such as air pollution or hazardous wastes. However, before 1992, states had not managed to adopt a comprehensive legal framework for the conservation and management of biological resources. The CBD fills this gap and provides the first umbrella agreement addressing both the conservation and use of all biological resources.

The CBD was adopted in 1992 in the form of a binding framework treaty. Its three main goals are the conservation of biological diversity, the sustainable use of its components,[10] and the fair and equitable sharing of the benefits derived from the use of genetic resources (Article 1 CBD). The Convention reaffirms the cornerstone principle of state sovereignty over resources that grants states sovereign rights to exploit their own resources pursuant to their own environmental policies, together with the responsibility to ensure that activities within their own jurisdiction or control do not cause damage to the environment of other states or areas beyond the limits of national jurisdiction. The Convention, however, innovates in bringing a new qualification to the principle of sovereignty. It introduces the notion that the conservation of biological diversity is a 'common concern of humankind', whereby states have a duty to cooperate in the sustainable management of resources found under their jurisdiction.

The CBD provides a number of general obligations for member states. In particular, these include a commitment to develop national strategies, plans or programmes for the conservation and sustainable use of biological diversity. Member states must also integrate, as far as possible, and as appropriate, the conservation and sustainable use of biological diversity into relevant sectoral or cross-sectoral plans, programmes and policies. Generally, member states are required to promote the sustainable use of biological resources by: integrating consideration of the conservation and sustainable use of biological resources into national decision-making; adopting measures relating to the use of biological resources to avoid or minimize adverse impacts on biological diversity; protecting and encouraging customary use of biological resources in accordance with traditional cultural practices that are compatible with conservation or sustainable use requirements; supporting local populations to develop and implement remedial action in degraded areas where biological diversity has been reduced; and encouraging cooperation between its governmental authorities and its private sector in developing methods for sustainable use of biological resources (Article 10 CBD).

Conservation under the CBD is to be achieved in two main ways. First, the Convention emphasizes *in situ* conservation which proposes the conservation of genes, species and ecosystems in the surroundings where they have developed their distinctive properties by establishing protected areas, rehabilitating degraded ecosystems and adopting legislation to protect endangered species.[11] *In situ* conservation implies, among other things: the development of guidelines for protected areas; the regulation of biological resources; the promotion of the protection of ecosystems and natural habitats and the maintenance of viable populations of species in natural surroundings; the promotion of environmentally sound and sustainable development in adjacent

[10] Sustainable use is defined under Article 2 of the CBD as the use of components of biological diversity in a way and at a rate that does not lead to the long-term decline of biological diversity, thereby maintaining its potential to meet the needs and aspirations of present and future generations.

[11] Article 2 of the CBD defines *in situ* conditions as 'conditions where genetic resources exist within ecosystems and natural habitats, and, in the case of domesticated or cultivated species, in the surroundings where they have developed their distinctive properties'.

areas; the rehabilitation and restoration of degraded ecosystems and the promotion of the recovery of threatened species; controlling the risks associated with the use of living modified organisms; controlling alien species; seeking compatibility between present and future use; developing necessary legislation to protect threatened species or populations; regulating any processes or activities found to have an adverse impact; and providing financial support for *in situ* conservation, especially to developing countries (Article 8 CBD).

Secondly, supplementary *ex situ* conservation outside the natural habitats of the protected biodiversity components is also proposed. *Ex situ* conservation requires the use of gene banks and zoological and botanical gardens to conserve species, which can contribute to saving endangered species. *Ex situ* measures are preferably undertaken in the country of origin. They include a duty to maintain facilities for the conservation of, and research on, plants, animals and microorganisms; to seek the rehabilitation of threatened species and their reintroduction into their natural habitats; to regulate the collection of biological resources from natural habitats for *ex situ* conservation so as not to unnecessarily threaten ecosystems and *in situ* populations of species; and to provide financial support for *ex situ* conservation, especially to developing countries (Article 9 CBD).

The CBD addresses a number of other issues of specific interest in the context of plant genetic resources. It imposes a duty on all member states to: respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity; promote their wider application with the approval and involvement of the holders of such knowledge, innovations and practices; and encourage the equitable sharing of the benefits arising from the utilization of such knowledge, innovations and practices (Article 8(j) CBD). The Conference of the Parties (COP) has addressed the implementation of Article 8(j) in different ways. An *ad hoc* open-ended inter-sessional working group was established at COP 4 to give more importance to issues related to TK.[12] The Working Group is mandated with the task of giving advice on legal and other means of protection of the knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant to the conservation and sustainable use of biological diversity. Further, COP 5 adopted a specific programme of work which aims at fostering the participation of local and indigenous communities in all aspects of the implementation of Article 8(j).[13] Member states are also requested to protect and encourage customary use of biological resources in accordance with traditional cultural practices that are compatible with conservation or sustainable use requirements (Article 10 CBD).

The CBD also provides a general legal framework regulating access to biological resources and the sharing of benefits arising from their use. The question of access is closely related to the issue of property rights and the legal status of biological resources under international law. Access has progressively become a contentious issue as the development of genetic engineering provides new ways to acquire IPRs over inventions derived from biological resources. As a result, since much of the world's biodiversity is found in developing countries,[14] the question of access became one of central importance in the CBD negotiations.

[12] Decision IV/9. Implementation of Article 8(j) and related provisions, in Decisions Adopted by the Conference of the Parties to the Convention on Biological Diversity at its Fourth Meeting, Bratislava, 4–15 May 1998, UN Doc. UNEP/CBD/COP/4/27 (1998).

[13] Programme of Work on the Implementation of Article 8(j) and Related Provisions of the Convention on Biological Diversity, in Decisions Adopted by the Conference of the Parties to the Convention on Biological Diversity at its Fifth Meeting, Nairobi, 15–26 May 2000, UN Doc. UNEP/CBD/COP/5/23 (2000).

[14] An important exception is Australia, which is both developed and 'megadiverse'.

The Convention attempts to provide a framework which both respects donor countries' sovereign rights over their biological and genetic resources and facilitates access by users. Access must therefore be provided on 'mutually agreed terms' and is subject to the 'prior informed consent' of the country of origin (Article 15 CBD). Further, the CBD provides that donor countries of microorganisms, plants or animals used commercially have the right to a fair share of the benefits derived from their use. Benefit-sharing, as conceived under the Convention and the Bonn Guidelines adopted in 2002, can take the form of monetary benefits, such as access fees; up-front payments; payment of royalties; licence fees in case of commercialization; research funding; and joint ventures. Benefit-sharing can also take the form of non-monetary benefits such as the sharing of research and development results; collaboration, cooperation and contribution in scientific research and development programmes; participation in product development; admittance to *ex situ* facilities of genetic resources and to databases; training related to genetic resources; and access to scientific information relevant to conservation and sustainable use of biological diversity (Bonn Guidelines, 2002).

The Convention goes further than the general regime provided by Article 15 and specifically provides for technology transfer as an invaluable instrument for the effective implementation of the Convention. In fact, Article 16 specifically recognizes the need to facilitate the transfer of technologies that are relevant to the conservation and sustainable use of biological diversity, or make use of genetic resources and do not cause significant damage to the environment.

The CBD is noteworthy in the context of international environmental agreements for offering a Statement on the relationship between the management of biological and genetic resources and IPRs. Article 16 clearly indicates that IPRs are not to undermine the working of the Convention. The actual relationship of the CBD with the TRIPS Agreement is an issue that has not yet found a specific answer. This is partly due to the fact that a clear-cut answer to this question would remove some of the grey areas that currently allow different states to take different views on this matter.

The agreement reached on the substantive provisions of the Convention was partly dependent on the willingness of developed countries to provide financial resources to subsidize developing countries' compliance with the proposed regime. As a result, the Convention requests the allocation of 'new and additional financial resources' to enable developing countries to meet the 'agreed full incremental costs' of implementing measures which fulfil the obligations of this Convention (Article 20 CBD). The importance of financial commitments for developing countries is illustrated by the fact that developing countries have the possibility, under the Convention, of making the implementation of their commitments dependent on the effective implementation by developed countries of their commitments related to financial resources and transfer of technology. In practice, developed countries discharge their financial commitments through the Global Environment Facility (GEF), which has operated the financial mechanism since the entry into force of the CBD.[15]

The institutional structure of the CBD includes a number of bodies. These include the Conference of the Parties, a Subsidiary Body on Scientific, Technical and Technological Advice (SBSTTA), and the Secretariat. The Conference of the Parties, which brings together all member states, is generally mandated with keeping the implementation of the Convention under review. More specifically, it reviews progress under the Convention, identifies new priorities to be pursued, sets work plans for members, amends the Convention, creates expert advisory bodies, reviews progress reports by member nations and collaborates with other international organizations and agree-

[15] See Chapter 6 for further developments on the GEF.

ments. Periodic state reports to the Conference of the Parties constitute one of the main monitoring instruments instituted under the Convention. State parties must report on the means they have adopted to implement the objectives of the Convention and the level of success of such measures. The Conference of the Parties has launched a number of thematic programmes covering, for instance, the biodiversity of inland waters, forests, marine and coastal areas, dry lands and agricultural lands, agricultural biodiversity, and cross-cutting issues such as the control of alien invasive species, strengthening the capacity of member countries in taxonomy, and the development of indicators of biodiversity loss.

The SBSTTA has been established to provide expert advice to other organs of the Convention. It is a multidisciplinary expert body which has the mandate to: provide scientific and technical assessments of the status of biological diversity and of the effects of types of measures taken in accordance with the Convention; identify innovative, efficient and state-of-the-art technologies and know-how relating to the conservation and sustainable use of biological diversity, and advise on the ways and means of promoting development and/or transferring such technologies; and provide advice on scientific programmes and international cooperation in research and development related to conservation and sustainable use of biological diversity. The CBD functions on a daily basis through a Secretariat situated in Montreal, which organizes meetings, drafts documents, assists member governments in the implementation of programmes, and coordinates with other international organizations to collect and disseminate information.

The CBD provides for the adoption of protocols. To date, only one instrument, the protocol on biosafety, has been adopted.[16] The Cartagena Protocol has been adopted in response to concerns over the negative environmental and health effects of some genetic engineering developments. The Protocol seeks to regulate some aspects of the transboundary movement of living modified organisms, in particular bio-engineered agricultural goods. Its aim is to ensure that a sufficient level of protection is achieved so that the transfer of living modified organisms does not entail adverse effects on the conservation and use of biodiversity. The Protocol also recognizes that the risks to human health posed by modified organisms are closely related to the risk they pose to biodiversity. The Protocol is put in practice through a procedure for 'advanced informed agreement'.[17] This imposes a duty on the exporter of a living modified organism falling under the scope of the Protocol to provide at least the information listed in Annex I to the Protocol. In the case of seeds or live animals, importing countries have the right to restrict imports in order to minimize possible adverse effects on the conservation and sustainable use of biodiversity.[18] One of the most significant elements of the Protocol is that a decision to refuse an import can be taken even in the absence of full scientific certainty regarding the extent of the potential adverse effects. In the case of commodities to be used as food or feed, the procedure is generally less onerous for the exporter and does not include an obligation to notify the importing country of each shipment, even though the importing country can generally restrict importations of a specific commodity.

2.3.2 The International Treaty on Plant Genetic Resources for Food and Agriculture[19]

The international legal regime for the conservation and use of agricultural plant

[16] Cartagena Protocol on Biosafety to the Convention on Biological Diversity, Montreal, 20 January 2000, reprinted in 39 ILM 1027 (2000).
[17] Article 7 ff. of the Cartagena Protocol, Note 16 above.
[18] Article 11 of the Cartagena Protocol, Note 16 above.
[19] Author: Philippe Cullet, with the help of Danuta Szymura Berglas.

genetic resources has been marked by significant changes over the past few decades. Traditionally, plant genetic resources for food and agriculture (PGRFA) were freely exchanged on the basis that PGRFA constituted a common heritage of humankind. As a result, PGRFA could not be appropriated. These principles were reflected in the practice of the CGIAR and were embodied in the International Undertaking adopted by the FAO Conference in 1983 (FAO Resolution 8/83).

It affirmed the principle that plant genetic resources are a heritage of humankind that should be made available without restriction to anyone. This covers not only traditional cultivars and wild species but also varieties developed by scientists in laboratories. The International Undertaking was adopted as a non-binding conference resolution. However, the emphasis on the free availability of PGRFA proved to be unacceptable to some developed countries that already had interests in genetic engineering. Broader acceptance of the International Undertaking was only achieved after the FAO Conference passed interpretative resolutions in 1989 and 1991.[20] These resolutions affirm the need to balance the rights of formal innovators as breeders of commercial varieties and breeders' lines on the one hand, with the rights of informal innovators of farmers' varieties on the other. Resolution 4/89 recognizes that plant breeders' rights, as provided for in UPOV Convention, are not inconsistent with the Undertaking, and simultaneously recognizes farmers' rights as defined in Resolution 5/89. Resolution 3/91 recognizes the sovereign rights of nations over their own genetic resources.

Further revision of the International Undertaking has been prompted by the growing importance of biological resources at the international level. In 1992, Agenda 21 called for the strengthening of the FAO Global System on Plant Genetic Resources, and its adjustment in accordance with the outcome of negotiations on the CBD. Resolution 3 of the Final Act to the CBD recognized that certain matters which the Convention had not addressed, such as the issue of access to *ex situ* collections not acquired in accordance with the Convention, and the realization of farmers' rights, were to be dealt with by the FAO's Global System on Plant Genetic Resources, of which the International Undertaking was the cornerstone. The FAO Conference provided the framework for the revision of the International Undertaking in its Resolution 7/93, which called on member states to generally harmonize the Undertaking with the provisions of the CBD, to address the issue of access to plant genetic resources, including the question of *ex situ* collections not addressed in the CBD, and specifically to ensure that the new instrument would foster the realization of farmers' rights. The negotiations for the revision of the Undertaking in harmony with the Convention began with the First Extraordinary Session of the Commission on Plant Genetic Resources in November 1994 and continued until the adoption of the Undertaking as a Treaty on 3 November 2001.[21]

The new Undertaking is now known as the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA).[22] The Treaty was the object of arduous negotiations that led to a final consensus text that was acceptable to all the states present, apart from the United States and Japan, who abstained from voting upon the text.

The overall objectives of the ITPGRFA are significantly different from those of the 1983 Undertaking. The Treaty, reflecting the new orientation given by the CBD, emphasizes the conservation of PGRFA, their sustainable use and benefit sharing. The guiding principles for these three

[20] Res. 4/89, Note 8 above and Res. 5/89, Note 8 above.

[21] Negotiating documents can be found on the web site of the Commission on Genetic Resources for Food and Agriculture at http://www.fao.org/ag/cgrfa/default.htm

[22] International Treaty on Plant Genetic Resources for Food and Agriculture, Rome, 3 November 2001 (hereafter ITPGRFA).

objectives are the promotion of sustainable agriculture and food security.

The ITPGRFA addresses a number of issues pertaining to the conservation and use of plant genetic resources. In other words, the Treaty focuses on issues not addressed in other international treaties, such as farmers' rights, but it does not directly address patents or plant breeders' rights as covered in the TRIPS Agreement and the UPOV Convention, respectively.[23] The ITPGRFA is the first treaty providing a legal framework that not only recognizes the need for conservation and sustainable use of plant genetic resources for food and agriculture, but also delineates a regime for access and benefit sharing (ABS), and in this process provides direct and indirect links to intellectual property right instruments. Secondly, it directly links plant genetic resource conservation, IPRs, sustainable agriculture and food security. Thirdly, the ITPGRFA provides the first multilateral system of ABS for PGRFA. Fourthly, it includes a section on farmers' rights. The ITPGRFA gives recognition to farmers' contribution to conserving and enhancing plant genetic resources for food and agriculture. It further gives broad guidelines to states concerning the scope of the rights to be protected under this heading, but overall devolves the responsibility for realizing farmers' rights to member states. This includes the protection of TK, farmers' entitlement to a part of benefit-sharing arrangements and the right to participate in decision-making regarding the management of plant genetic resources. However, the treaty is silent with regard to farmers' rights over their landraces. In fact, the 'recognition' of farmers' contribution to plant genetic resource conservation and enhancement does not include any property rights. In this context, the only rights that are recognized are the residual rights to save, use, exchange and sell farm-saved seeds.

An important consequence of the Treaty is that guidance concerning the management of CGIAR collections will, in the future, come from the Treaty's Governing Body.[24] This is significant because the CGIAR has historically largely worked on the basis of the sharing of resources and knowledge. In recent years, following the adoption of the TRIPS Agreement in particular, the CGIAR has progressively modified its position with regard to the grant of IPRs.[25] New guiding principles on intellectual property were adopted to harmonize CGIAR's core principle that designated germplasm is held in trust for the world community with the recognition of various forms of property rights, including sovereign rights, farmers' rights and private rights.[26] In principle, the IARCs do not apply intellectual property protection to their designated germplasm and require recipients to observe the same conditions. They also refrain from asserting IPRs over the products of their research. An exception to this rule is made in cases where the assertion of IPRs facilitates technology transfer or otherwise protects developing countries' interests. The CGIAR also requires that any IPRs on the IARCs' output should be assigned to the Centre and not an individual. While the guiding principles generally seek to contain the monopoly elements of IPRs such as patents, plant breeders' rights are specifically welcomed. Recipients of germplasm can apply for plant breeders' rights as long as this does not prevent others from using the original materials in their own breeding programmes.

In practice, the ITPGRFA is of greater

[23] On the relationship between the Treaty and intellectual property right instruments, see, for example, Article 12.3.f of the ITPGRFA, Note 22 above.

[24] See Article 15 of the ITPGRFA, Note 22 above.

[25] See, for example, CGIAR, 'Progress Report on IPR Matters and Proposal for Review of Plant Breeding', Mid-Term Meeting, 1999, Beijing, CGIAR Doc. MTM/99/20.

[26] See CGIAR (1999) *CGIAR Center Statements on Genetic Resources, Intellectual Property Rights, and Biotechnology*. CGIAR, Washington, DC. Individual IARCs have also adopted intellectual property right policies; see, for example, International Maize and Wheat Improvement Center, Policy on Intellectual Property (2000).

importance for PGRFA covered under the Multilateral System. Concerning the resources covered, member states must adopt an integrated approach to the exploration, conservation and sustainable use of PGRFA. Their specific obligations include the need to inventory PGRFA, promote their collection, promote farmers' and local communities' efforts to manage and conserve their PGRFA on-farm, promote *in situ* conservation of wild-crop relatives and wild plants for food production, and cooperate to promote the development of an efficient and sustainable system of *ex situ* conservation. Further, member states are to take measures to eliminate threats to PGRFA. Alongside conservation obligations, member states must also promote the sustainable use of PGRFA. Measures include the promotion of agricultural policies that foster the development and maintenance of diverse farming systems; an emphasis on research which enhances and conserves biological diversity by maximizing intra- and inter-specific variation for the benefit of farmers; the promotion of plant breeding efforts which strengthen the capacity to develop varieties particularly adapted to social, economic and ecological conditions; the promotion of the use of local and locally adapted crops, varieties and underutilized species; and the support of the wider use of diverse varieties and species in on-farm management, conservation and sustainable use of crops.

The main institutional innovation of the ITPGRFA is found in the novel scheme devised to regulate ABS of PGRFA covered under the Treaty. The Multilateral System is a consequence of the policy reversal, which has seen PGRFA pass from the domain of a shared resource to one that is under the sovereignty of states. This is a direct consequence of the link between the Treaty and the CBD that provides for national sovereignty over biological resources. The underlying reason for the inclusion of a system of facilitated access is that the sovereign rights of states over their PGRFA are qualified by the recognition that these resources are a common concern of humankind and that all countries depend largely on PGRFA that originated in other countries. As a result, donor countries have full control over their PGRFA but there are strict limitations on their ability to restrict access to other states.

Under the Multilateral System, a series of crops (listed in Annex I) which account for most of – but not all – human nutrition are covered by a provision under which member states agree to provide facilitated access. As per the ITPGRFA, access is to be provided only for the purpose of utilization and conservation for research, breeding and training for food and agriculture. As a result of the recognition of PGRFA as a common concern, access has to be accorded expeditiously. Member states must also make available all passport data and, subject to applicable law, any other associated available non-confidential descriptive information. Concerning material that is under development by farmers or breeders at the time when access is requested, the Treaty gives the country of origin the right to delay access during the period of development. This was one of the most difficult parts of the Treaty negotiations related to the treatment of IPRs. The compromise solution is that recipients of PGRFA cannot claim IPRs that limit the facilitated access to the PGRFA, or their genetic parts or components, in the form received from the Multilateral System. Further, PGRFA accessed under the Multilateral System must also be made available to other interested parties by the recipient under the conditions laid out by the Treaty. This provision, which stops the appropriation of isolated components from material accessed under the Multilateral System, was strongly opposed by some countries that had determined that this would stifle innovation. On the other hand, when intellectual property or other property rights already protect the PGRFA in question, access can only take place in conformity with the treaties regulating those particular kinds of property rights. As is the case with some other treaties, like the Biosafety Protocol, the ITPGRFA refuses to establish a hierarchy between itself and other related treaties, such as IPRs treaties. This leaves the door open for conflicting

interpretation at the time of implementation.

The question of access is closely related to that of benefit sharing. In fact, the benefit-sharing regime constitutes another part of the bargaining process that seeks to make PGRFA a common concern of humankind. Access is to be facilitated and, as a result, donors are granted the right to receive some form of benefits in return. In fact, the Treaty goes one step further in asserting that the premise for benefit sharing is, in the first place, the fact that access to PGRFA constitutes in itself an important benefit for recipient countries. Different types of benefit-sharing mechanisms are provided for under the Treaty: these include the exchange of information, access to and transfer of technology, capacity building, and the sharing of the benefits arising from commercialization. With regard to the sharing of information, the Treaty envisages that member states will, for instance, provide catalogues and inventories, information on technologies, and the results of technical, scientific and socio-economic research. The Treaty provides a specific information system, the Global Information System, which will generally serve to provide all member states with relevant information concerning crops in the Multilateral System. Concerning technology transfer, the Treaty only provides a general obligation to facilitate access to technologies for the conservation, characterization, evaluation and use of PGRFA, which is further qualified by the fact that access to such technologies is subject to applicable property rights. In the case of developing countries, specific mention is made of the fact that even technologies protected by IPRs should be transferred under 'fair and most favourable terms', in particular in the case of technologies for use in conservation as well as technologies for the benefit of farmers in developing countries. Beyond information and technology transfers, benefit sharing can take the form of capacity-building measures. These include the establishment of programmes for scientific and technical education and training in conservation and sustainable use of PGRFA, and the development of facilities for conservation and sustainable use of PGRFA. Finally, the Treaty provides for the sharing of monetary benefits. These include, for instance, the involvement of the private sector in developing countries in research and technology development. Further, the standard Material Transfer Agreement, through which facilitated access will be implemented, will include a requirement that an equitable share of the benefits arising from the commercialization of a product that incorporates material accessed through the Multilateral System will have to be paid to the Trust Account set up under the Treaty. The benefits that arise under the benefit-sharing arrangements must be primarily directed to farmers who conserve and sustainably use PGRFA.

The ITPGRFA deals with a number of other issues of relevance in the context of the management of plant genetic resources. Importantly, the Treaty specifically addresses the issue of *ex situ* collections held in trust by the International Agricultural Research Centres (IARCs) of the CGIAR. The Centres, which have signed agreements with the FAO concerning their collections, are now invited to sign new agreements with the Treaty's Governing Body. These agreements will determine that the access provisions of the ITPGRFA will govern the collections of the Centres that are part of the Annex I list. This will, however, only cover materials collected after the entry into force of the Treaty and that fall within its scope. The Centres are also obliged to provide preferential treatment to countries that provide material to their gene banks and are not to request any Material Transfer Agreement if a country of origin wants to access its own material. Generally, the Centres recognize the authority of the Governing Body to provide policy guidance relating to their *ex situ* collections.

The Governing Body, a body comprising all member states, will oversee the implementation of the ITPGRFA. Its functions will generally be to promote the full implementation of the Treaty. This will include the adoption of plans and programmes for the implementation of this Treaty, the establishment of subsidiary

bodies as may be necessary and the consideration and adoption of amendments – by consensus – to the Treaty.

Overall, the Treaty, which constitutes the outcome of many years of negotiations, is noteworthy for providing the first international recognition of farmers' rights in a binding instrument. The provisions concerning ABS, which will constitute the most important part of the Treaty in practice, are largely lacking in specificity. This reflects the difficult balancing that the negotiators had to provide between the interests of developed and developing countries, big private seed companies and small farmers and a number of other actors in between.

2.3.3 The law and policy in the World Trade Organization[27]

From GATT to the WTO

With the advent of the World Trade Organization (WTO), which succeeded the General Agreement on Tariffs and Trade (GATT) 1947, the legal framework bearing on PGR, and indirectly on TK, has significantly changed by its actual or potential implications (Cottier, 1992). The stronger rules governing trade in goods (GATT), the General Agreement on Trade in Services (GATS), and in particular the TRIPS agreement set a new context for transactions involving PGR. A relatively well-developed dispute settlement mechanism accords this framework greater efficacy. However, while trade in PGR falls under current WTO law, the protection of TK so far has not been addressed in treaty law. It was placed on the agenda for further discussions under the TRIPS Agreement at the 2001 Doha Ministerial Conference.[28]

The WTO system today rests on three major pillars: the rules affecting trade in goods, trade in services and the protection of IPRs.[29] The WTO system is an important part of the law on PGR and the protection of TK. Most of the WTO law potentially applies to goods and services relating to these subjects. This is true for the GATT 1994 and the sectoral agreements, in particular the Agreement on Agriculture and the Agreement on Sanitary and Phytosanitary Measures.[30] Of paramount importance is the TRIPS Agreement, as it directly addresses intellectual property protection of PGR.

International trade in PGR has always been subject to the multilateral disciplines of the GATT 1947. In principle, this agreement also applied to trade in agricultural commodities derived from PGR, and the GATT 1994 continues to do so. The most-favoured nation treatment (Articles I, II) and national treatment (Article III) principles have to be respected. The prohibition of quantitative import restrictions also applies, with narrowly defined exemptions (Article XI), as well as general exceptions (Articles XX, XI). The rules on import licensing (Article XIII) and other pertinent provisions, in particular the disciplines on tariffs (Articles II, VII and XXVIII), transit (Article V), fees and formalities, (Article VIII), anti-dumping (Article VI), marks of origin (Article IX), transparency and judicial review (Article X), state trading and monopolies (Article XVII), and balance of payment exemptions (Articles XII, XVIII) all apply to agricultural products. The same was true of important sectoral agreements, such as the old Agreement on Technical Barriers to Trade. However, under GATT 1947 there were many exemptions, and disciplines remained weak. Key provisions on

[27] Author: Thomas Cottier.

[28] WTO, Ministerial Declaration, para. 19, WT/MIN(01)/DEC/1 (20 November 2001).

[29] There are 12 side agreements to the GATT 1994 and no fewer than six understandings, all of which elaborate further on its provisions. The rules on services trade have been further developed after the Uruguay Round to cover the regulation of financial services and telecommunications. There are four plurilateral agreements, of which the Agreement on Government Procurement is particularly important.

[30] Other agreements not dealt with in this survey may also be of importance, such as the Agreement on Import Licensing Procedures and the Agreement on Safeguards. The GATS is relevant for consulting and other professional services in connection with PGR and TK.

subsidies to agricultural products were weak.[31]

The system has witnessed substantial structural changes since the 1970s, which accelerated with the Uruguay Round and will further evolve with forthcoming rounds of trade liberalization. These are of importance in the present context. First, international trade law has progressively developed beyond market access and begun to increasingly entail harmonization of domestic regulations. It has moved towards a global law of integration. Secondly, WTO law now has a relatively effective dispute settlement mechanism which no longer leaves non-compliance without costs and disadvantages for governments and nations. Both of these aspects place WTO law in the forefront of international legal developments. It is worth recalling these developments before turning to the contents of WTO law pertinent to PGR and TK.

From tariffs to farm support levels and intellectual property protection

Trade policy in the early post-Second World War era focused on the gradual reduction of tariffs and the elimination of preferential systems. The GATT 1947 provided, in essence, a framework for a gradual process of tariff reduction. The provisions of the GATT 1947 were originally designed to accompany this process and to avoid frustration and circumvention by other means: in particular quantitative restrictions, subsidies, or discriminatory taxes on imports. Indeed, the gradual reduction, and even elimination, of tariffs within customs unions and free trade areas increasingly shifted the emphasis on non-tariff measures. Quantitative restrictions, export subsidies, anti-dumping duties, technical standards, balance of payment measures, labelling requirements, import licensing, rules on government procurement, and 'voluntary' export restraints (VERs) all became additional and widely used instruments. With their beginnings in the Kennedy Round, such non-tariff barriers became, besides the classical process of tariff-reduction, the main objects of trade negotiations in the Tokyo Round.

A third generation of trade barriers was brought in focus during the 1980s. It encompasses a number of issues, ranging from domestic farm support to restrictive regulation of service industries, of investments and, finally, the protection of intellectual property. These subjects stem from different fields of law, public and private, but have in common that they are all mainly part of the general domestic legal system. They are not directly geared to classical international trade relations but they have been affecting such relations more and more in terms of limiting market access. There is a link between the above factors and some of the great political difficulties in reaching final agreement in key issues of the Uruguay Round, such as reduction of agricultural support systems, and conditions for investment and liberalization of trade in services. The main difficulties to be settled in the area of TRIPS have similar roots. The issue of patentability of pharmaceuticals, foodstuffs, or of living matter – namely, the problem of how far exceptions to patentability should be allowed to go, or, in copyright, how the relationships of authors, producers, performers and users should be arranged – are perhaps the most prominent examples in showing how far international negotiations and regulations have penetrated socially, ethically or culturally sensitive issues of the domestic political process.

More than ever before, international trade regulation today seeks to provide fair competition in a globalizing market econ-

[31] The USA, for example, benefited from a general waiver. The European Community, in defence of its Common Agricultural Policy (CAP), often retaliated by using its veto power on the establishment of dispute settlement panels or on the adoption of reports, leaving them without much consequence in practice. Switzerland enjoyed major benefits in its protocol of accession, making it one of the most protectionist Members in agriculture, despite a relatively high level of food imports.

omy. Foreign and domestic economic affairs can no longer be separated; and the increasing importance and attention paid to foreign policy in general, formerly of real interest often merely to a few, is a natural effect of such developments. This is also true in the context of trade in PGR and the protection of TK, which entail an inextricable linkage of domestic and foreign policy issues.

International dispute settlement and enforcement

The dispute settlement mechanism of the WTO is a unique and powerful instrument in international economic relations. The Dispute Settlement Body (DSB) of the WTO has now developed a substantial jurisprudence that is unique in a highly fragmented and decentralized system of international law.[32] In a nutshell, the WTO dispute settlement mechanism consists of three phases. Upon the filing of a complaint, consultations are to be held among the Parties. Failing a successful conclusion by negotiations (the result in approximately two-thirds of all disputes), the complaining Party is entitled to ask the DSB for the establishment of a panel.[33]

A panel, once established, regularly consists of trade officials and/or academics knowledgeable in the field of law at issue, most commonly economists and lawyers. It is assisted by the WTO Secretariat (specifically the Legal Affairs Division and the operational divisions concerned). Parties submit legal briefs to the panel and two or three oral hearings are held at which interested Third Parties may also take part and express their legal arguments. Panel proceedings are conducted in a judicial manner and on the basis of a set of customary and written procedural rules developed over time. The panel may also conduct hearings with independent experts in the field. The panel drafts a report which is circulated to the Parties for comments before a final version is submitted to the DSB. If the report is adopted in the absence of a reverse consensus, it proceeds to implementation. However, the Parties, in particular the losing Party, may object and file an appeal to the Appellate Body, a standing panel of seven senior international trade lawyers. Appeals are generally limited to specific points, which may also be raised by the winning Party. The jurisdiction of the Appellate Body is limited to questions of law. It does not extend to factual assessment and evidence, apart from certain exceptions. The report of the Appellate Body is again submitted to the DSB. The losing Party no longer has the right to object, and the report is adopted unless there is consensus (including the winning Party) to reject the report. It goes without saying that this procedure in practical terms entails automatic adoption of the report, and the losing Party is obliged to comply. The entire proceedings from the filing of the complaint are subject to very tight time limits. Proceedings are usually completed, including the appellate phase, within 18 months. Longer periods have been found to be necessary in more complex cases, but even those are far shorter than most domestic, let alone international, judicial proceedings.

The decision forms the basis for implementation. The losing Party, in principle, is obliged to implement the recommendation. However, it has the option to offer compensation which is rarely accepted and often not of interest to the winning Party. Often the amount of compensation is set by a panel of arbitration – which is normally composed of the original panel – in terms of surcharge tariffs equivalent to the financial losses incurred since the unlawful measure

[32] From 1995 to the beginning of 2001, 103 disputes were resolved. Of these, 48 or almost half were settled without recourse to adjudication (see Duk Park and Umbricht, 2001).

[33] Importantly, complaints on nullification and impairment of benefits do not entail only violations of treaty provisions, but may also comprise so-called non-violation complaints. This course of action, albeit rare, envisages the protection of legitimate expectations as to conditions of competition, and bars Members from taking measures in bad faith that nullify trade concessions granted in previous negotiations.

was put in place. Failing implementation and compensation, the winning Party may obtain the right to suspend concessions (retaliation). Countries are free to target areas not directly linked to the subject matter in dispute. Retaliation for failure to comply with the GATT 1994 and the related sectoral agreements may thus eventually result in measures in the field of services or intellectual property, and vice versa. Targeted goods may also be alternated in order to increase pressure to comply. The USA, for example, operates special *carousel* legislation to this effect.

The enforcement system benefits large markets with retaliatory powers. It is one of the weaknesses and inequities of the system that it leaves small markets and weaker countries with little power to retaliate. The system has not reached a level of multilateral implementation that would encourage all Members to participate in such action. It is therefore not surprising that large countries rank among the main users. At the same time, it is important to emphasize that the WTO dispute settlement mechanism has also been used successfully by developing and smaller countries alike, as compliance with adopted reports has also proved to be in the long-term interest of large Members. Except for three major cases, compliance so far has shown an impressive and successful record. In difficult cases, the new system has shown the efficacy of its novel features, unheard of so far in international law: it eliminated veto or exit powers, and made rulings subject to monitoring of implementation and effective enforcement. It is not a coincidence that two of the cases that have proved to be major stumbling blocks, the banana dispute[34] and the dispute on hormone-treated meat,[35] essentially addressed problems of production and trade in agriculture which – besides services – is one of the most highly regulated and protected sectors. Tensions with national or regional law abound. The mandatory nature of the system, and the imposition of substantial surcharge tariffs following denial of implementation by the European Communities, almost brought about crises and major trade wars with the USA. For the first time, problems could no longer be evaded by veto, and the Parties had to go through a long and protracted process of negotiating a political settlement. This exit no longer exists, and the tensions show, more than anything else, the deep and fundamental changes of the rules of the game brought about by the advent of the WTO.

The system applies to all areas of WTO law alike. While panels are barred from creating additional obligations or rights, the process of interpretation inherently entails a refinement of the law. Indeed, in between trade rounds, the main emphasis of WTO legal activities is on dispute settlement and the development of case law. In the field of PGR, no cases have so far been decided. Yet, related areas, such as sanitary and phytosanitary measures, have been repeatedly scrutinized and a substantial body of law has evolved. This is also true for intellectual property protection, which until 1995 had never been the subject of mandatory dispute settlement. The DSU fully applies to the TRIPS Agreement.[36] So far, nine requests for consultations in the field have been filed, many of them relating either to rules on patent protection for pharmaceuticals and agricultural chemical products or enforcement of IPRs.[37] In some of these cases, mutually agreed solutions between the Parties involved were notified (Baracol, 2001, pp. 37–41). The relative success of consultations may be because the TRIPS provisions are detailed and provide good guidance in assessing rights and obligations.

[34] European Communities – Regime for the Importation, Sale and Distribution of Bananas, WT/DS27/AB/R (9 September 1997).

[35] European Communities – Measures Concerning Meat and Meat Products, WT/DS26 and 48/AB/R (16 January 1998).

[36] The only exception concerned so-called non-violation complaints, which were excluded until the year 2000.

[37] Cf. see above, Annex 1, giving an overview of WTO disputes in the field of intellectual property rights.

The panel stage was reached by two disputes relating to obligations of countries to provide a so-called mailbox for the filing of patent applications even before the general transitional period of 10 years elapsed. In India–Patent Protection for Pharmaceutical and Chemical Products,[38] the Panel and the Appellate Body ruled upon a complaint by the USA (and also one by the European Communities) that administrative practices, short of a legal basis, did not amount to an adequate compliance with these obligations. On substance, important cases addressed the scope of fair use exceptions in patent law and in copyright law. A further case addressed the protection of trademarks and trade names under US law in the context of economic sanctions against Cuba.

The Agreement on Agriculture

The advent of the WTO was accompanied by a comprehensive Agreement on Agriculture, the main feature of which was the regulation of import restrictions (Horber, 1995, p. 51). Member states were obliged, by way of their tariff schedules, to reduce tariffs in agriculture by 36% on average (at least 15% per tariff line) by 2001. This leaves most countries with still very high bound tariffs, the reduction of which will be the subject of further rounds of negotiations.[39] Independently of tariff protection, a minimum market access right beginning with 3% of domestic consumption and increasing to 5% had to be realized by 2001. Domestic support by product-related subsidies – formerly typically a domestic issue – had to be reduced by 20%. Further decreases are to be expected in the Doha Round. On the other hand, Members obtained full autonomy in the use of non-product-related payments (the Green Box), which has been mainly used to finance direct assistance, and has become the basis of a new agricultural policy in both the European Communities and Switzerland. The shift from product-related support (often causing excess production) to direct payments has paved the way for ecological reforms. Overall, they bear the potential for sustainable agriculture, which, short of pressures from the global trading system, would have been difficult to bring about domestically. Finally, the agreement obliges countries to reduce export subsidies by 36% (on the basis of 1986/1988 rates) on agricultural products and transformed products (such as chocolates or biscuits) and a quantitative reduction by 21% of subsidized products. The Doha Ministerial Declaration of November 2001 pledged to work towards further reduction, with a view to eliminating all export subsidies in agriculture, given their often detrimental impact on developing countries.[40]

The Agreement on the Application of Sanitary and Phytosanitary Measures

A new Agreement on Sanitary and Phytosanitary Measures (SPS Agreement) regulating foodstuffs was adopted, replacing the application of the Technical Barriers to Trade (TBT) Agreement in this field. It was elaborated during the Uruguay Round and addresses the problem of excessive foods standards that may unreasonably impair trade in agricultural products. Such standards also exist in the field of genetic resources, in particular seeds. The Agreement essentially seeks to encourage the use of international foods standards developed by international bodies, such as the joint Codex Alimentarius Committee of the FAO and the World Health Organization (WHO). However, it allows Members to apply their own and stricter standards, provided that they are in a position to scientifically demonstrate that such higher standards are required in order to respond to the level of risk that has been defined. The complex

[38] WT/DS50/AB/R (19 December 1997).

[39] For example, bound agricultural tariffs in the European Communities amount to an average of 17.3% and in Switzerland to 34%. WTO, Trade Policy Review: European Union 2000, xix (2000) and WTO, Trade Policy Review: Switzerland and Liechtenstein, xxi (2000).

[40] WTO, Ministerial Declaration, para. 13, WT/MIN(01)/DEC/1 (20 November 2001).

agreement allows Members to invoke the precautionary principle. Since 1995, it has given rise to a number of complex disputes which sought to define the proper levels of protection and of judicial review of such measures, the *Hormones* case being the most prominent and controversial. It is important to note that it has remained unclear whether the SPS Agreement also applies to genetically modified organisms (GMOs). Moreover, it may partly overlap and conflict with the Cartagena Protocol on Biosafety which allows trade restrictions mainly, but not only, for reasons of environmental protection.

The Agreement on Trade-related Aspects of Intellectual Property Rights

CHANGING PARADIGMS AND THE ADVENT OF THE AGREEMENT

While the law of PGR outside trade-related matters has been defined primarily by the instruments discussed above, in particular the CBD, the ITPGRFA and the CGIAR System and its rules and policies, the inclusion of intellectual property protection in the WTO system with the adoption of the TRIPS Agreement has fundamentally altered previous equations. New conditions and incentives for investment have been set in global law, exclusive rights granted, and a new relationship between protected products and those pertaining to the public domain has emerged.

It is important to note that international efforts to bring about adequate IPR protection did not start with the TRIPS Agreement. The international dimension of intellectual property is not new. In fact, as early as the 1880s, it ranged among the first efforts in international economic law to bring about shared perceptions. The many agreements and unions, in particular those administered by the World Intellectual Property Organization (WIPO), provide ample evidence of this tradition. Other organizations and forums, in particular the OECD and the UN General Assembly, also show a considerable record of work and recommendations to the extent that IPRs are related to the transfer of technology or to competition.[41] Yet, due largely to differing perceptions as to the role of intellectual property in the process of economic development, as well as diverging traditions among industrialized countries, substantive global standards, in particular concerning industrial property, remained largely of an open and permissive nature. Throughout the 1970s and the early 1980s attempts to introduce more specific norms largely failed due to such differences; the unsuccessful effort to revise the Paris Convention is a case in point. Moreover, an effective, swift and simple system of dispute settlement is lacking within the WIPO, and no standards existed in the treaty system on the effective enforcement of IPRs. The thrust of worldwide cooperation therefore has focused mainly on achieving national treatment for foreign nationals and, with the exception of international copyright law, on the important field of acquisition and administration of rights, namely by using effective ways to simplify the international registration of national trademarks, designs and patents.

The difficulties mentioned in achieving global progress in traditional international forums have led to the increased linkage of IPR protection with trade policies, and the marriage has attracted considerable scholarly attention ever since.[42] The negotiations

[41] The negotiations on the law of the sea in the 1970s (UNCLOS III) provide a classic example of extensive efforts to negotiate on intellectual property rights in order to bring about such transfers in the field of deep seabed mining.

[42] Outside the regional context of the European Communities, such linkages were first established by the 1984 US Trade Act, and further reinforced in 1988 with controversial provisions and procedures allowing for retaliation in market access in goods and services against countries having unfair and distorting regimes on intellectual property, whether or not these were in conflict with current international obligations. The IPR protection–trade linkage in domestic US law, and bilateral and regional efforts, such as the Caribbean Basin Initiative, were certainly a source of inspiration in bringing the subject into the GATT system upon the initiative of the US when the Punta del Este Mandate for the Uruguay Round was drafted and agreed upon in 1986.

that led to the adoption of the TRIPS Agreement were initiated by the USA.[43] The initiative was particularly based upon the estimates made by the USA, whose industries in 1986 suffered losses of some 24 billion dollars due to inadequate protection of intellectual property and related investments. In the beginning, the European Community was reluctant to commit itself on the issue, but in the course of the negotiations, it gradually became one of the major *demandeurs*.

The 7-year negotiations went through three phases. A long process of fact-finding, which also worked as a tool for mutual education, led to comprehensive proposals by various Contracting Parties. After the mid-term review of Montreal in December 1989 and the April 1990 ministerial decision, intensive negotiations took place. Work was successfully concluded in December 1991, when the draft TRIPS Agreement was wrapped up as part of the 'Dunkel Text'. During the last phase, efforts were aimed at keeping the results achieved and at avoiding their being jeopardized by counter-productive new proposals in the field of intellectual property, or by a deadlocking of negotiations regarding other issues such as agriculture or audio-visual services. Unlike during the first two phases, the last phase was marked by conflicting interests between the USA and the European Communities on copyright issues (cultural aspects, blank tapes levies). The results achieved were made possible due to various factors, many of which are interesting for the purposes of a general assessment of the importance of intellectual property. To a great extent they exceeded the initial expectations.

THE SUBJECT MATTER OF THE AGREEMENT

Signed on 15 April 1994, the TRIPS Agreement lays down the essential elements for the minimum level of protection that countries must accord to intellectual achievements. It covers all fields of intellectual property: copyright, topographies of integrated circuits, trademarks and service marks, geographical indications, industrial designs, patents for inventions and trade secrets. It defines rights and obligations under these different forms of intellectual property. Generally speaking, such rights include the exclusive right to make, use, sell, offer to sell, and import products protected by IPRs. In addition, member states undertake to provide detailed rules guaranteeing the procedures and remedies that must be available at the national level for IPRs to be effectively enforced. Members had to implement the TRIPS Agreement by the end of the transitional period, which ended for developing countries in 2000. The transition period will end in 2005 for rules on product patents, except for least developed countries. With the adoption of the TRIPS Agreement, intellectual property is now an integral part of the multilateral trading system.

GENERAL PROVISIONS

The Agreement strengthens the national treatment principle as contained in the relevant existing international conventions (Article 3). However, it includes a concept of trade law that is new in the field of intellectual property law: the most-favoured nation (MFN) principle (Article 4). A WTO Member must accord automatically to other WTO Members the same favourable treatment it has granted to a third country on a bilateral basis. The MFN particularly strengthens the position of smaller countries *vis-à-vis* the big trading powers. As a result of the TRIPS Agreement and its MFN clause, a bilateral agreement concluded, for example, between the USA and Japan on the improvement of registration procedures will also be extended *erga omnes* so as to avoid any incompatibility with the TRIPS obligations.

[43] At the end of the Tokyo Round, the USA and the European Communities unsuccessfully launched a draft Anti-Counterfeit Code. Subsequent work did not materialize due to opposition by developing countries. Eventually, the protection of intellectual property rights was included in the 1986 negotiating mandate of Punta del Este, and – as a political compromise – limited to its 'trade-related aspects'.

The TRIPS Agreement contains two general provisions that are of potential importance for PGR and TK. First, Article 7 states:

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

This general provision was proposed by developing countries and intended to safeguard the proper balance between private rights and public goods against one-sided and detrimental effects that IPRs may have, and in order to promote their use as incentives for foreign investment and transfer of technology. The provision is of a horizontal nature and applies to all provisions of the agreement. Given its nature, it is not independently operational but forms the interpretation of other provisions, in particular when defining the proper relationship between exclusive rights and public goods. We shall return to the impact of the provision on PGR and TK.

Secondly, the TRIPS Agreement also recognizes in Article 8 that intellectual property regulations do not prevent Members from adopting measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic development. Members are equally entitled to take measures against the abuse of IPRs or against practices that unreasonably restrain trade or adversely affect the international transfer of technology. The effects of intellectual property protection may entail some potential for conflicts with antitrust law. However, Article 8 is constrained by the proviso (introduced upon the motion of industrialized countries) that such measures are required to be consistent with the other provisions of the TRIPS Agreement. Article 8.1 therefore does not allow deviation from the operational provisions of the TRIPS Agreement. As to Article 8.2, addressing the abuse of IPRs and competition, it is important to note that the authority of Members to take measures is further detailed in Article 40 of the TRIPS Agreement, which preserves the rights of Members to take action under their own national or regional competition rules. The issue of restrictive business practices is addressed in the TRIPS Agreement only in terms of the matter being left to national jurisdiction. It is expected that it will be brought into focus again in future negotiations, when a fine balance will have to be struck between protection of investments, exclusive rights resulting from those investments, and the efficient functioning of global competition.[44]

Article 8, like Article 7, forms interpretation and has to be taken into account in defining the scope and impact of rights and obligations under the TRIPS Agreement. The provisions of Article 8.1 played an important role in recent disputes and discussions relating to compulsory licensing of patents over new essential medicines (for HIV/AIDS). The Ministerial Declaration adopted at Doha confirmed its importance, while leaving operational rules, in particular on compulsory licensing of patents (Article 31), unchanged.[45]

COPYRIGHT AND RELATED (NEIGHBOURING) RIGHTS

Copyright entails the protection of expressions of mental activity not only in the arts and sciences, but also in modern technology. Its scope is limited and it does not pro-

[44] The Doha Ministerial Conference adopted the following work programme on competition in para. 25, without opening negotiations on the subject. 'In the period until the Fifth Session, further work in the Working Group on the Interaction between Trade and Competition Policy will focus on the clarification of: core principles, including transparency, non-discrimination and procedural fairness, and provisions on hardcore cartels; modalities for voluntary cooperation; and support for progressive reinforcement of competition institutions in developing countries through capacity building. Full account shall be taken of the needs of developing and least-developed country participants and appropriate flexibility provided to address them'.

[45] WTO, Ministerial Declaration, para. 17, WT/MIN(01)/DEC/1 (20 November 2001).

tect substance, ideas, procedures and methods (including mathematical concepts). It inherently does not require a high level of originality. The same is true for neighbouring rights that address the rights of performing artists, film broadcasters and phonogram producers.

Copyright and neighbouring rights protection is important for the protection of TK to the extent that it is expressed. Traditional music and performances are at the forefront. Moreover, it is important for electronic data collections on PGR and for programming specifically designed for this field. It covers books and publications on the subject. Otherwise, copyright is not suitable for addressing PGR and knowledge *per se*. It is rather by protecting the cultural background and its diversity that copyright indirectly makes a contribution to their valuation and reward.

The provisions of the TRIPS Agreement on copyright amend the traditional rules of the Berne Convention and essentially focus on new technologies: the protection of computer programs, including exclusive rental rights, and of electronic databases (Articles 10 and 11); the protection of rights of interpreters and broadcasting organizations against unauthorized reproduction, the worldwide protection of phonograms against unauthorized copying and reproduction, and the recognition of exclusive rental rights over phonograms (with the possibility of preventing the rental in particular of new copies, subject to existing rules which are limited to an obligation of equitable remuneration) (Article 14); and the protection of cinematographic works to avoid widespread copying materially impairing the exclusive right of reproduction (Article 11). The human rights dimension of copyright was explicitly excluded (due to pressure from the US film industry), as the TRIPS Agreement (and dispute settlement) does not encompass moral rights under Article 6bis of the Berne Convention (Article 9.1).

The agreement prescribes a minimum duration of protection of 50 years (Article 12), except for broadcasters' rights, for which the period is 20 years (Article 14.5) from the end of the calendar year of authorized publication, making, or broadcasting. In other words, unlike in many national laws, there is no *post mortem auctoris* term of protection.[46] The protection of performers' rights, which was traditionally limited to European civil law countries, is for the first time dealt with in a multilateral treaty of a wider geographical coverage.

TRADEMARKS

Trademark protection is of key importance in identifying and individualizing products originating from PGR and/or based on TK. Seeds and varieties can be sold under trademarks, and TK can be protected indirectly by linking it to trade names and supplementary qualifications, using terms not in the public domain.

The function of trademarks consists in identifying the origin of the product and allowing the consumer to distinguish different products. For the first time in international economic law, the TRIPS Agreement provides a globally uniform definition of trademarks (for goods and services), including protection of combinations of colours (but not requiring protection for sound marks) (Article 15). Protection of internationally well-known trademarks (i.e. without registration) applies not only to products but also to services. Trademarks cannot be used to bar parallel imports unless there is a risk of confusion for the consumer (Article 16.1). The term of protection is no less than 7 years, with indefinite possibility of renewal (Article 18). A possibility of cancellation of trademarks exists only after a minimal time period of non-use of 3 years (Article 19). There is a prohibition of other requirements for the use of trademarks (e.g. requirement for use to be only in combination with another trademark), and (unlike in patents) a complete prohibition of compulsory licensing (Articles 20, 21). The TRIPS Agreement entails a significant

[46] The provisions are of particular significance for producers of computer programs and phonograms, against counterfeiting and piracy.

improvement of trademark and service mark protection in countries other than in Western Europe and North America. The protection of internationally well-known trademarks is thereby enhanced.

PROTECTION OF GEOGRAPHICAL INDICATIONS

Geographical indications are a prime instrument for protecting products derived from PGR and TK, as this protection (other than trademarks) requires the quality, reputation or other characteristic of a product to be essentially attributable to its geographical origin. This allows the protection not merely of the uniqueness of the product but also the uniqueness of its origin and TK at that place.[47]

As a general rule, protection is ensured by an obligation to introduce laws protecting against deception of the consumer as to the true geographical origin and quality of the product and against other forms of unfair competition (Article 22). The same rule also applies to the use of names in the course of trade to the extent that they are used in a manner to mislead the public (Article 24.8). Members are barred from registration of trademarks which mislead the public as to the origin of the product (Article 22.3). Protection thus takes place on a case-by-case basis without prescribing registration in international law.

A higher (absolute) level of protection was introduced for wines and spirits (Article 23). These products enjoy privileged protection. The use of geographical names for products produced elsewhere is barred, even where the true origin of the product is indicated or where it is accompanied by qualifications such as 'kind, type, style, imitation' or the like. However, such protection does not extend to denominations in customary use. Homonymous indications, namely similar names for different origins, are protected, subject to measures against consumer deceptions. In particular, denominations of wines and spirits continuously using foreign locations, but in use before 1984 and in good faith, are grandfathered and cannot be challenged (Article 24.4). Generally, no protection exists against use of denominations if they are in generic use in the common language of a Member. The same is true for products of the vine if they coincide with the customary name of a grape variety (Article 24.6).

The TRIPS Agreement contains obligations to further develop protection of geographical indications. An international system for notification and registration for geographical indications of wines should be negotiated (Article 23.4). Member states pledged to enter into negotiations in order to further extend the coverage of protection, in particular to foodstuffs. In this respect, the Council for TRIPS initiated preparatory work by the end of 1998, but no results have been achieved.[48] The Doha Ministerial Conference reiterated the agreement to negotiate on the subject of an international registration of wines, but a similarly strong commitment exists for the further development of protection for other geographical indications. The Conference merely noted that the TRIPS Council would deal with these issues pursuant to procedures adopted for implementation issues.[49]

INDUSTRIAL DESIGNS

The Agreement adopts, for the first time in international economic law, a common def-

[47] For example: Flocons de Quinoa, 'Quinoa Real', a grain cultivated in the Andes (Bolivia) 3000 m above sea level, which has specific qualities due to cultivation at this altitude.

[48] See the press release on: http://www.wto.org/wto/new/pu101298.htm

[49] Doha Ministerial Declaration, para. 18: 'With a view to completing the work started in the Council for Trade-Related Aspects of Intellectual Property Rights (Council for TRIPS) on the implementation of Article 23.4, we agree to negotiate the establishment of a multilateral system of notification and registration of geographical indications for wines and spirits by the Fifth Session of the Ministerial Conference. We note that issues related to the extension of the protection of geographical indications provided for in Article 23 to products other than wines and spirits will be addressed in the Council for TRIPS pursuant to paragraph 12 of this Declaration'.

inition of industrial designs. However, countries remain free to require either novelty or originality (Article 25). There is an obligation for Members to provide for protection of creations in the field of textiles so as to take into account the short life cycle (fashion) of such design creations. The term of protection must be no less than 10 years (Article 26.3). The provision on textile designs is of particular importance to the design industry. Registration may become important for traditional crafts and the preservation of cultural identity and tradition, to the extent that they bring about innovative patterns that qualify, in terms of originality, for design protection. Moreover, copyright protection can also be used in many countries as a possible way to protect designs without any registration requirements.

TOPOGRAPHIES OF INTEGRATED CIRCUITS

The protection of integrated circuits is not of any relevance here except for the fact that it is an example of *sui generis* protection, derived for a specific technology. The TRIPS Agreement, building upon the Treaty on Intellectual Property in Respect of Integrated Circuits (Washington Treaty), grants exclusive rights, including the right to prevent the importation of goods containing the topographies. Limited exceptions (only stock in hand or ordered before notice of an unlawful act) exist in favour of the *bona fide* buyer of counterfeited goods (Articles 36, 37). The term of protection extends to at least 10 years (Article 38). It entails a prohibition of reciprocity treatment in the national laws of industrialized countries through the MFN clause.

PATENTS FOR INVENTIONS

The provisions on patents for inventions of the TRIPS Agreement define, to a large extent, the legal conditions applicable to genetic resources and TK. The provisions of the TRIPS Agreement considerably enhance the protection for breeding and genetic engineering, and have changed the legal relationship between genetic resources and TK on the one hand, and newly appropriated technological advances on the other. They are of considerable significance not only for the chemical and pharmaceutical industries, but also for all other sectors with active patent-oriented strategies. In the field of biotechnology, the limitation of patentability to microorganisms reflects the minimal consensus in a worldwide controversial discussion, which will continue as the present state of the law neither satisfies the long-term needs of the industry nor of developing countries.

The TRIPS Agreement establishes the principle of non-discrimination as to the fields of technology, the place of invention, and the country of production (Article 27.1), thus barring differential treatment of different fields of technology. Members are not allowed to apply different rules on patent protection depending on different fields of technology: no special rules for genetic engineering can be adopted. The minimum term of protection is 20 years (Article 33). The Agreement entails an obligation to provide product protection in the field of pharmaceuticals and foodstuffs. Developing countries are obliged to introduce such protection by 2005. In the meantime, inventions are to be protected by so-called 'pipeline' protection, which amounts to quasi-exclusive rights by means of administrative measures and marketing approval until full patent protection takes effect (Articles 70.8, 70.9).[50]

The TRIPS Agreement recognizes general exceptions from patenting in order to protect the *ordre public* and morality, including the protection of human, plant and animal life and health or to avoid serious prejudice to the environment. Importantly, exceptions can only operate if at the same time the Member prohibits commercial exploitation of the product. On the other hand, it is not sufficient to preclude patenting only because the law prohibits the exploitation of the invention. Beyond these general exceptions, the TRIPS Agree-

[50] The scope of these rules was expounded in India-Patent Protection. WT/DS50/AB/R, 19 December 1997.

ment recognizes special exemptions for which Members may qualify. Negotiations on these points were extremely difficult, and they resulted in what was considered a provisional solution. Plants and animals other than microorganisms, and essentially biological processes for the production of plants and animals, may be excluded from patentability. But there is an obligation to grant patent protection of inventions relating to microorganisms and essentially biological processes. It entails an obligation to provide an effective *sui generis* protection for plant varieties. Members may choose to operate under the UPOV Convention. They may choose to design new and innovative schemes of protection, taking into account considerations of benefit sharing and access regulation under the CBD. Finally, they may, in addition, opt for special or general patent protection, either exclusively or in accumulation. We shall return to these distinctions in a close examination of patenting of life forms in different countries (see Section 2.4).

Article 27.3(b) was meant to be of a provisional nature and the provision was subject to a review 4 years after the entry into force of the TRIPS Agreement in 1995. The review has not produced any substantive results. The Doha Ministerial Conference reiterated the mandate to pursue the review. Importantly, this mandate includes an examination of the relationship of the TRIPS Agreement, the CBD, the protection of TK and folklore, and other new developments raised by Members:

> 19. We instruct the Council for TRIPS, in pursuing its work programme including under the review of Article 27.3(b), the review of the implementation of the TRIPS Agreement under Article 71.1 and the work foreseen pursuant to paragraph 12 of this declaration, to examine, *inter alia*, the relationship between the TRIPS Agreement and the Convention on Biological Diversity, the protection of traditional knowledge and folklore, and other relevant new developments raised by Members pursuant to Article 71.1. In undertaking this work, the TRIPs Council shall be guided by the objectives and principles set out in Articles 7 and 8 of the TRIPS Agreement and shall take fully into account the development dimension.[51]

This statement implies recognition of the fact that the scope of patentability cannot be settled independently of other relevant instruments and the interests at stake, and of the importance to obtain an overall balance in accordance with the goals set forth in Article 7 of the Agreement.

PROTECTION OF TRADE SECRETS (UNDISCLOSED INFORMATION)

Protection of undisclosed information is of importance to TK to the extent that the circle of knowledgeable people is restricted. This may be of importance to healers and shamans in the use of genetic resources.

Protection of undisclosed information was introduced by the TRIPS Agreement and recognized as an intellectual property right (Article 2) going beyond mere protection against unfair competition. The notion of undisclosed information is defined. A secret is protected if it is not generally known or readily accessible to persons within circles that normally deal with the information. It must have commercial value and is subject to reasonable measures of precaution in order to keep the secret (Article 39). The TRIPS Agreement establishes the right to take action against infringement of trade secrets, including damages to be paid by enterprises which knew, or should have known, that the information given included trade secrets (Article 39.2, note 10; Article 45). It entails an obligation to protect test data concerning pharmaceuticals or agricultural chemical products that utilize new chemical entities in the course of an approval procedure against unfair commercial use (Article 39.3).

The adoption of provisions on the protection of trade secrets – for the first time in a multilateral treaty – is of particular importance in the light of growing use of trade secrets by enterprises in various fields. Pro-

[51] WTO, Ministerial Declaration, para. 19, WT/MIN(01)/DEC/1 (20 November 2001).

tection of test data against unfair commercial use will need to be developed in clearer terms (as for example in European Community law through a 5-year limitation of protection). The provision is likely to result in licensing of test data and therefore in sharing the burden *ex post* of research efforts. The protection against further disclosure of test data by the competent authorities is of particular interest to the agrochemical and pharmaceutical industries, whose products are subject to marketing approval procedures.

ENFORCEMENT AND TRANSPARENCY

The TRIPS Agreement entails a code of detailed rules on enforcement. The right to have access to review by judicial authorities of final administrative decisions is established (Articles 42, 41.4, 62.5). The TRIPS Agreement stipulates the right to obtain injunctions (Article 44), damages (Article 45) and other remedies, including destruction of products and means of production (Articles 46, 59). Protection against misuse of procedures by the right holder (harassment) is established (Article 48).

The right to obtain provisional measures (Article 50) and suspension of the release of *prima facie* counterfeit or pirated goods for a period of ten working days, and if need be, against payment of security, is established (Articles 51–57). An obligation to make laws and agreements publicly available provides for transparency. In particular, the obligation to publish or make publicly available final judicial and administrative decisions of general application (precedents) expresses fundamental precepts of the rule of law.

The enforcement provisions require legislative amendments, particularly in developing countries and in Central and Eastern Europe. The adoption and implementation of such provisions are of key importance to an effective protection and enforcement of IPRs. From a long-term perspective, they improve the means by which to tackle intellectual property problems through judicial channels. Before the adoption of the TRIPS Agreement, only diplomatic interventions were possible. The requirement to publish precedents will improve transparency in many countries, including Western Europe.

WTO law and genetic resources

In conclusion, the law of the WTO is of paramount importance for genetic resources and TK. The regulatory level and the effective dispute settlement mechanism place it at the heart of future developments. The brief survey above indicates that regulation of the two areas is affected by a number of agreements, including the GATT 1994, the Agreement on Agriculture, the Agreement on Sanitary and Phytosanitary Measures and the TRIPS Agreement. We realize that the impact of WTO rules is not limited to the particular problem of intellectual property and patenting. It also affects other forms of IPRs. Moreover, other regulatory areas, in particular tariffs and other trade regulations, such as phytosanitary measures, affect it too. There is an overall potential for promoting the use of, and the protection of, genetic resources and TK in the different policy instruments of the WTO. But there is a potential to render such protection and promotion more difficult if it is not sufficiently taken into account in future law-making. It will be a matter of examining these problems in the full context of other agreements and domestic regulations. The ministerial mandate of Doha to examine the issue of patenting life forms in a wider context, including the protection of TK, is encouraging. It is a necessary first step towards a larger coherence and has to be expanded to all pertinent issues alike.

2.3.4 The International Union for the Protection of New Varieties of Plants (UPOV)[52]

The UPOV Convention was first signed in 1961 to provide a form of legal protection of

[52] Author: Philippe Cullet with the assistance of Danuta Szymura Berglas.

plant varieties for Western European countries.[53] It seeks to protect new varieties of plants both in the interest of agricultural development and of plant breeders. Although it did not introduce patents, UPOV sought from the outset to provide incentives to the private sector to engage in commercial plant breeding, by introducing so-called plant breeders' rights. Despite the distinction between patents and plant breeders' rights, the two share several basic characteristics: they provide exclusive commercial rights to holders, reward an inventive process, and are granted for a limited period of time, after which they pass into the public domain.

More specifically, UPOV recognizes the exclusive rights of individual plant breeders to produce or reproduce protected varieties, to condition them for the purpose of propagation, to offer them for sale, to commercialize them, including exporting and importing them, and to stock them with a view to production or commercialization (Article 14.1 UPOV). Protection under UPOV is granted for developed or discovered plant varieties that are new, distinct, uniform and stable (Article 5 UPOV). The concept of novelty under UPOV is noteworthy because it differs from the approach under patent law. Under UPOV, a variety is novel if it has not been sold or otherwise disposed of for purposes of exploitation of the variety. Novelty is thus defined in relation to commercialization and not by the fact that the variety did not previously exist. UPOV gives a specific time frame for the application of novelty. To be novel, a variety must not have been commercialized in the country where the application is filed for more than a year before the application, and in other member countries for more than 4 years.[54] The criterion of distinctness requires that the protected variety should be clearly distinguishable from any other variety whose existence is a matter of common knowledge at the time of the filing of the application. Stability is obtained if the variety remains true to its description after repeated reproduction or propagation. Finally, uniformity implies that the variety remains true to the original in its relevant characteristics when propagated.

The UPOV Convention has been revised several times since 1961: in 1972, 1978 and 1991. At present some states are parties to the 1978 Act and some states are parties to the 1991 Act. Non-member states that wish to join the UPOV regime at present must join under the 1991 Act, but there is no obligation for existing member states to ratify the latest version of the convention if they do not wish to.

The revisions to the Convention have generally served to progressively strengthen plant breeders' rights. The 1991 version, for instance, extends breeders' rights to all production and reproduction of their varieties and to species as well as general and specific plant varieties. This now also includes so-called 'essentially derived varieties' (Article 14.5 of UPOV). Protection of an essentially derived variety is obtained if the variety is predominantly derived from the initial variety and retains its essential characteristics. It must also be clearly distinguishable from the initial variety while conforming to the initial variety in the expression of the essential characteristics.

One of the main distinguishing features of the original UPOV regime is that the recognition of plant breeders' rights is circumscribed by two main exceptions. First, under the 1978 version of the Convention, the so-called 'farmer's privilege' allows farmers to re-use propagating material from the previous year's harvest and to freely exchange seeds of protected varieties with other farmers. Secondly, plant breeders' rights do not extend to acts done privately and for non-commercial purposes or for experimental purposes, and do not extend to the use of the protected variety for the purpose of breeding other varieties and the

[53] Note that this section introduces the UPOV Convention in general. Further developments concerning plant breeders' rights can be found in Chapter 3.

[54] Article 6 of the UPOV Convention. In the case of other member countries, the relevant timeline is 6 years for trees and vines.

right to commercialize such other varieties. The 1991 version of the Convention, by strengthening plant breeders' rights, has conversely limited existing exceptions. The remaining exceptions include acts done privately and for non-commercial purposes, experiments, and for the breeding and exploitation of other varieties. Breeders are now granted exclusive rights to harvested materials and the distinction between discovery and development of varieties has been eliminated.[55] Further, the right to save seed is no longer guaranteed as the farmer's privilege has been made optional.

As noted, plant breeders' rights were first conceived as an alternative to patent rights. As a result, UPOV originally provided that the two kinds of IPRs should be kept separate. Under UPOV-1978, member states can, for instance, only offer protection through one form of IPRs. The grant of a PBR on a given variety implies that no other intellectual property right can be granted to the same variety. This restriction has been eliminated under UPOV-1991 and double protection is now allowed.

The UPOV Convention was first negotiated and ratified mostly by developed countries. It is only since the adoption of the TRIPS Agreement that more developing countries have progressively joined the Convention.[56] Even though developing countries did not participate in the development of this legal regime which is tailored for mechanized and large-scale agriculture, the rationale for joining it is that the UPOV regime is generally held to fulfil the conditions of a *sui generis* system as required under Article 27.3(b) of the TRIPS Agreement.[57]

2.4 Selected Regional and National Legal Frameworks[58]

2.4.1 Developing countries

Developing countries have adopted different strategies to respond to the need to introduce IPR frameworks in the field of plant genetic resources as required by the TRIPS Agreement. This section reviews a few of the initiatives that have been taken at the broad level of a whole continent (the African Model Legislation), at the regional level (Andean Community) and at the national level (Peru and India). This serves to illustrate different ways in which developing countries have faced the challenge of introducing IPR in the field of plant genetic resources.

The African continent: the OAU Model Legislation[59]

In the African continent, states have tried to respond individually and collectively to the challenge that the implementation of the TRIPS Agreement presents for most of them. Before the adoption of the TRIPS Agreement, most sub-Saharan African states, in particular the least developed ones among them, had not invested significant time and effort in developing IPR regimes in the field of plant genetic resources. The sudden need to implement the TRIPS Agreement has led African states to pursue different strategies. Some states have tried to develop national frameworks while others have tried to cooperate in the framework of existing regional IPR organizations.[60] Most states realized that the difficulties involved in devising a new framework for access and control over plant

[55] See, for example, Nijar and Ling (1994, p. 277).

[56] Overall, as of July 2002, out of 51 member states there were 16 developing country members, an overwhelming majority of them being Latin American countries, and with only four developing country members altogether from Africa and Asia.

[57] See, for example, WTO, Review of Article 27.3(b): The View of Switzerland, WTO Doc. IP/C/W/284 (2001).

[58] Authors: Philippe Cullet, Susette Biber-Klemm and Danuta Szymura Berglas.

[59] Author: Philippe Cullet.

[60] See, in particular, Annex 10 of the Agreement to revise the Bangui Agreement on the Creation of an African Intellectual Property Organization of 2 March 1977 and 24 February 1999, Bangui.

genetic resources and related knowledge necessitated an effort at a broader level. As a result, the Organization of African Unity (OAU) took on the task of negotiating among its member states a model law adapted to the African region that could be relied upon when introducing national legal frameworks concerning plant genetic resources.

The African Model Legislation for the Protection of Rights of Local Communities, Farmers, and Breeders and for the Regulation of Access to Biological Resources (Model Legislation) was finally adopted in 2000 after a period of consultations and negotiations. The Model Legislation pursues a number of inter-related goals. It generally seeks to ensure the sustainable management of biological resources. Within this broad objective, the Model Legislation focuses on a number of different issues. These include the question of access to biological resources, community rights, farmers' rights and plant breeders' rights.

The Model Legislation first seeks to reassert countries' sovereign rights over their biological resources and proposes a system whereby access can only be granted with prior and informed consent of the state of origin of the biological resource, as well as of concerned communities.[61] Among the conditions laid down in the Model Legislation is one specifying that patents over life forms are not recognized on accessed biological resources. As a result, individuals or legal entities that collect biological resources are barred from applying for patents over biological resources accessed in accordance with the Model Legislation.[62]

After dealing with the issue of access and the conditions on which access can be granted, the Model Legislation defines three types of related property rights. First, it recognizes the collective rights of communities to their biological resources and the right to collectively benefit from their use, rights to their innovations, practices, knowledge and technology as well as the right to benefit collectively from their utilization.[63] In practice, these rights allow communities to prohibit access to their resources and knowledge, but only in cases where access would be detrimental to the integrity of their natural or cultural heritage.[64] The right to control access is strengthened with a right to receive at least 50% of the benefits derived from the commercial use of their resources or knowledge. The duty to channel the benefits back to the communities is put on the state.[65] The Model Legislation also provides for the recognition of community IPRs. These rights include the rights of communities to community innovation, practice, knowledge or technology.[66] Apart from the specific indication that registration is not a condition for the protection of community IPRs, the Model Legislation does not provide a complete framework for community IPRs, a task that must be undertaken by individual countries adopting the Model Legislation.

The Model Legislation goes on to define farmers' rights. Farmers' rights include the protection of TK relevant to plant and animal genetic resources; the right to an equitable share of benefits arising from the use of plant and animal genetic resources; the right to participate in making decisions on matters related to the conservation and sustainable use of plant and animal genetic resources; the right to save, use, exchange and sell farm-saved seed or propagating material; and the right to use a commercial breeder's variety to develop other varieties.[67]

Besides the recognition of community

[61] See Articles 3–8 of the African Model Legislation for the Protection of Rights of Local Communities, Farmers and Breeders and for the Regulation of Access to Biological Resources, 2000.
[62] Article 9 of the African Model Legislation, note 61 above.
[63] Articles 17–19 of the African Model Legislation, note 61 above.
[64] Article 20 of the African Model Legislation, note 61 above.
[65] Article 23 of the African Model Legislation, note 61 above.
[66] Article 24 of the African Model Legislation, note 61 above.
[67] Articles 25–27 of the African Model Legislation, note 61 above.

rights and farmers' rights, the Model Legislation also defines plant breeders' rights along the lines of the model provided by the UPOV Convention. The Model Legislation seeks to provide a comprehensive regime that includes not only the rights of farmers and communities but also the rights of commercial breeders. The underlying reason for including plant breeders' rights in these provisions is that the Model Legislation proposes a plant breeders' rights regime that is much more balanced than the UPOV version. The Model Legislation thus provides broad exemptions to the rights of breeders and also gives significant latitude to member states to restrict the rights for reasons of public interest.[68]

On the whole, the Model Legislation seeks to provide a framework that takes into account the requirements of Article 27.3(b) of the TRIPS Agreement. At the same time, it tries to go further and to recognize the specific needs of African countries by emphasizing the need for a strict regime on ABS, as well as the need for the recognition of other rights, such as the collective rights of communities and farmers' rights. While the Model Legislation constitutes a source of inspiration for all states that are developing legal frameworks in this field, it has not been widely adopted in the form it received at the level of the OAU. This is probably due, in part, to the fact that while the plant breeders' rights regime proposed under the Model Legislation goes some way towards meeting the criteria of an 'effective' *sui generis* system under the TRIPS Agreement, the rather stringent restrictions imposed on the rights of commercial breeders, and the introduction of farmers' rights as well as community rights, make it a rather controversial instrument at the international level. This is the case although it probably constitutes an appropriate starting point for most African countries, and is much more adapted to local circumstances and needs than a regime solely based on the UPOV Convention.

Andean region[69]

THE ANDEAN COMMUNITY'S REGIME ON GENETIC RESOURCES AND TRADITIONAL KNOWLEDGE

The Andean region has been at the forefront of efforts to introduce legal frameworks to implement the access and benefit-sharing provisions of the CBD. This section surveys the region-wide regime on access to genetic resources and traditional knowledge and gives an overview of its implementation in the Peruvian legislation.

Two Decisions of the Andean Community are relevant for its regime on access to genetic resources and TK: the 1996 Decision on a Common Regime on Access to Genetic Resources,[70] and Decision 486 on the Common Intellectual Property Regime.[71]

The 1996 Decision 391 of the Cartagena Agreement,[72] established a common regime on access to genetic resources. Its purposes are: (i) to establish the conditions for a just and equitable participation in the benefits of access; (ii) to lay the foundations for the recognition and valuation of the genetic resources and their by-products, and of their associated intangible components; (iii) to promote conservation and sustainable use of biological diversity; (iv) to promote the development of scientific, technological and technical capacities at all levels; and (v) to strengthen the negotiating

[68] Articles 43 and 45 of the African Model Legislation, note 61 above.

[69] Author: Susette Biber-Klemm.

[70] Andean Community Commission, Decision 391: Common Regime on Access to Genetic Resources, Caracas, Venezuela, 2 June 1996 http://www.comunidadandina.org/normativa/dec/D391.htm (English and Spanish).

[71] Decision 486: Régimen Común sobre Propiedad Industrial, Lima, Perú, a los catorce días del mes de setiembre del año dos mil.

[72] The Cartagena Agreement of 1969 (the Andean Subregional Integration Agreement), as revised by the Protocol of Trujillo of 1996, created the Andean Community. The Andean Community aims at the economic and social integration of its members in view of the creation of a Latin American Common Market. The members of the Andean Community are Bolivia, Colombia, Ecuador, Peru and Venezuela.

capacity of the member countries (Article 2).

The 'strategic value' of the know-how, innovations and practices of the native Afro-American and local communities, their historic contribution to the conservation and development of biological diversity, and the sustained use of its components are explicitly recognized in the preamble (paras 5 and 6). The close interdependence between the native populations and communities and their biological resources, and the need for its reinforcement, are acknowledged (para. 7).

The Decision's subject matter encompasses the genetic resources, their by-products and so-called 'intangible components'. By-products (*Producto derivado*) are defined as 'a molecule, a combination or mixture of natural molecules, including crude extracts of live or dead organisms of biological origin that come from the metabolism of living beings' (Article 1.7). The 'intangible components' are defined as all know-how, innovation or individual or collective practice with a real or potential value that is associated with the genetic resource, its by-products or the biological resource that contains them, whether or not protected by intellectual property regimes (Article 1.18). Thus the Decision explicitly includes not only genetic, but also biochemical information[73] and TK.

The Decision is based on the concept that genetic resources originating in a state, and their by-products, are goods belonging to the heritage of the state. As such, they are 'inalienable, not subject to prescription and not subject to seizure or similar measures'. This exclusive right of the state is independent of the property regimes applicable to the biological resources that contain the genetic or biochemical resources, or to the land on which they are located (Article 6). The state is the exclusive holder of the property rights over the genetic resources. This means that the genetic information contained in domesticated plants and crops bred by farmers and indigenous communities falls under the authority of the state, the individual holders not being allowed to decide about the use made of the genetic information.[74] Farmers and local communities have no rights either to the genetic information contained in their varieties, or to the biochemical information contained in, for instance, medicinal plants.

Neither does the Andean Community's regulation of Plant Breeders' Rights recognize any rights of farmers to their varieties.[75] The 'Common Provisions on the Protection of the Rights of Breeders of New Plant Varieties'[76] closely follows the UPOV regulations. Breeders' certificates are to be granted to persons who have created new, uniform, distinct and stable plant varieties: the term 'creation' meaning 'the production of a new variety by the application of scientific skills' (Article 4).

TK, however, remains under the authority of its authors. Member countries are obliged to 'recognize and value the rights and the authority of the native, Afro-American and local communities to decide about their know-how, innovations and traditional practices associated with genetic resources and their by-products' (Article 7).

This differentiation of the rights to genetic and biological resources and associated TK leads to a complex system and various 'layers' of access contracts in the Decisions ABS regime.[77]

Access contracts are to be concluded between the applicant and the state (Article

[73] The question being whether medicinal plants as such (i.e. biological resources) fall under the regulation or not (Ruiz Muller, 2003).

[74] As to the consequences of this regime on the rights of grassroot stakeholders in the ABS process, see Biber-Klemm, Chapter 7; similarly, Ruiz Muller (2003) and Rosell (1997).

[75] A narrow farmers' privilege for own (non-commercial) use is granted (Article 26).

[76] Decision 345: Régimen Común de Protección a los derechos de los Obtentores de Variedades Vegetales, Bogotá, Colombia, 21 October 1993.

[77] As to the problems generated by this system regarding the marketing of the information see Biber-Klemm, Chapter 7; similarly, Ruiz Muller (2003).

32), the latter defining the conditions for access (Article 17). In addition, so-called ancillary contracts defining the conditions for access have to be concluded between the applicant and the owner of the biological resource (land owner, possessor, manager; *ex-situ* facility; owner of the biological resource [Articles 41–44]). These contracts do not confer an independent right of access but depend on the main access contract with the National Authority (Article 42). If 'intangible components' are included in the research, the conditions for access have to be negotiated with their respective holder and to be included in an annex to the access contract (Article 35). So, in order to be allowed to access one resource, various layers of contracts with various stakeholders in different locations might have to be negotiated.[78]

In the case of failure to comply with the stipulations of the annex, the entire access contract can be nullified (Article 33).

The national intellectual property offices have to control compliance with the access regulations. Sanctions such as fines, confiscation, closing-down of establishments or disqualification from applying for new accesses may be imposed upon unauthorized access or transactions that are not protected by corresponding contracts (Articles 46 and 47). IPRs that have been obtained or developed on the basis of illicit access are not to be acknowledged by the Member Countries.

This control is reinforced by Decision 486 on the Common Intellectual Property Regime,[79] which, revising an earlier version, was adopted in 2000.[80] The Decision is specifically meant to implement the TRIPS Agreement and the CBD. With respect to access to genetic resources and traditional knowledge, the Decision stipulates the following: as in decision 319, the member states recognize the rights and faculties of local, indigenous and Afro-American communities to decide over their collective knowledge (Article 3). It narrows the possible scope of patents in excluding not only life forms, in whole or in part, as they are found in nature, natural biological processes and biological material which exist in nature, but also material that can be isolated from any life form, including genomes or germplasm (Article 15).

It provides a certain control of the legitimacy of access, as any application for a patent on an invention, obtained or developed from genetic resources, their derived products, or from TK shall include a copy of the access contract, or the copy of the document that accredits a licence or authorization of use from the community, respectively (Article 26). Patents granted on inventions obtained or developed from genetic resources or traditional knowledge, without presentation of a copy of the proper access contract or licence from the community, are to be nullified (Article 75), and any mark referring to elements of the cultures of indigenous, Afro-American or local communities shall not be registered without the community's express consent (Article 136).[81]

THE PERUVIAN REGIME ON ACCESS TO GENETIC RESOURCES AND TRADITIONAL KNOWLEDGE

In implementing the Andean framework, Peru has issued regulatory instruments on access to both genetic resources, and to TK. These are, with regard to the genetic resources, the 'Law on the Conservation and Sustainable Use of Biological Diversity'[82] and the 'Draft Regulation on Access to Genetic Resources'; with regard to TK,

[78] See the enumeration in Ruiz Muller (2003), Box 1.

[79] Decision 486: Régimen Común sobre Propiedad Industrial, Lima, Perú, a los catorce días del mes de setiembre del año dos mil.

[80] The following is based on information from GRAIN: Andean Community Adopts New IPR Law, 5 October 2000. http://www.mtnforum.org/resources/library/grain00a.htm (23 May 2004).

[81] See the critical assessment of this decision in the interview with Margarita Florez in the GRAIN information above, note 80.

[82] Ley sobre la conservación y aprovechamiento sostenible de la diversidad biológica, Ley Nº 26839. Accessible in Spanish on: http://www.grain.org/brl/brl-ley-peru-es.cfm

the 'Law introducing a Protection Regime for the Collective Knowledge of Indigenous Peoples derived from Biological Resources'.[83]

The Law on Conservation and Sustainable Use of Biodiversity is the implementation of the Convention on Biological Diversity. It is based on the designation in the constitution (Artículo 66º) of all natural resources (renewable and non-renewable) as the heritage of the state. It was enacted in 1997. The law adopts the Andean Pact regime of the state being owner of the genetic resources, independently of the ownership of the biological resources. Accordingly, the state is party to the access procedures (Artículo 27, 28). Access can be restricted or denied for reasons including conservation of resources and their ecosystems, and/or potential negative effects on essential elements of the cultural identity of the peoples involved, and for 'strategic' genetic resources[84] ('Recursos genéticos … calificados como estratégicos') (Article 29).

The 'Proposal of a Regulation on Access to Genetic Resources' establishes the procedure for gaining access.[85] It fixes the content of the request, determines the competent authorities and establishes the period of time granted to the authorities for the individual steps. It further spells out the minimum conditions the agreements must contain. As parties to the negotiations, it determines a state agency, and for the negotiations of the ancillary contracts the provider of the genetic resource – which can be the state, but also, for instance, an *ex situ* gene-bank or an indigenous people, including landowners or owners of the biological resources – and the purchaser/applicant. The conditions of compensation are to be negotiated with the provider[86] of the resource (Article 34). However, the main contract has to be negotiated with the competent state agency. The ancillary contracts 'can' (*podrán*) be concluded with the other involved stakeholders, the wording leaving open whether there is an obligation to involve them or not (Article 9). The financial benefits resulting from the access contract are to be set aside for a fund for the conservation, investigation and development of genetic resources. A directive council administers the fund, encompassing representatives from the involved ministries, universities teaching genetics, NGOs and indigenous peoples (Article 51). The fund is meant to support projects for the conservation and use of genetic resources, as well as to improve the scientific capacities of the universities conducting research

[83] Ley 27811: Régimen de protección de los conocimientos colectivos de los pueblos indígenas vinculados a los recursos biológicos (10 August 2002); http://www.concytec.gob.pe/infocyt/ley27811.html; http://www.grain.org/brl/peru-tk-2002–en.cfm. See also the overview in WIPO (without document number), Descriptions of National and Regional Experiences with Existing *sui generis* Measures and Laws for the Protection of TK; advance copy, WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore, Fifth Session, July 7–15, 2003. For medicinal plants there is specific legislation (Ley 27300 de aprovechamiento sostenible de las plantas medicinales, 8 July 2000).

[84] The draft regulation on Access on Genetic Resources defines 'Strategic Genetic Resources' as: 'Todo recurso que es nativo o no del Perú o que el Perú es su centro ancestral de diversificaciôn, que serve paragraphsatisfacer al menos una necesidad humana básica, que se sosepcha que tiene un potencial ceonico inusitado, que es naturalmente escaso a nivel mundial o endémico y natrualmente insustituible. La calida de recurso gehético stratégico es declarado expresamente por el Estado Peruano' (Article 2.39). However, the interdiction of the exportation of viable or primarily processed parts of the – commercially interesting – Maca plant (*Lepidium meyenil)* is based on the argument of the conservation of the national genetic heritage allowing exceptions of free trade (Decreto Supremo Nº 039–2003–AG, 8 December 2003).

[85] Propuesta de Reglamento sobre Acceso a los Recursos Geneticos. Version Abril-Julio 2001. Accessible under http://www.inrena.gob.pe/divbiol/reglamento-final-06–de-agosto.pdf (23 May 2004). The proposal is presently (summer 2004) in the parliamentary process; the final version not yet being known (personal information Begoña Venero, INDECOPI).

[86] The draft regulations define as provider the person, institution, indigenous people or other facility in the framework of Decision 391 and the present regulations … including the state.

in genetic resources, but also institutions that enable the negotiating capacity of the indigenous people (Article 49).

So, the proposed Peruvian regime on access to genetic resources hardly strengthens the position of local farmers and other holders of genetic resources and is even a rather weak implementation of the participatory farmers' rights as stipulated in the ITPGRFA.

In turn, the right of indigenous peoples to their collective knowledge is explicitly recognized and regulated in the 'Law introducing a Protection Regime for the Collective Knowledge of Indigenous Peoples derived from Biological Resources'.[87] This law is based on a provision in the Peruvian Law on Intellectual Property that gives the Ministry of Industry, Tourism, Integration and International Trade the competence to 'establish a regime to protect and possibly register the knowledge of native and farming communities'.[88] The term 'indigenous peoples' is broadly defined as 'aboriginal peoples holding rights that existed prior to the formation of the Peruvian state, maintaining a culture of their own, occupying a specific territorial area and recognising themselves as such. These include … rural and native communities' (Article 2(a)).

The law creates a *sui generis* right to the *collective knowledge* that belongs to the *communities* of the indigenous peoples (and explicitly not to its individual members) (Article 10). This collective knowledge is considered a part of the cultural heritage of the indigenous peoples (Article 11). Therefore the rights of the indigenous peoples to their collective knowledge are inalienable and not extinguishable (Article 12). The present generations preserve, develop and administer their collective knowledge for their own benefit and for that of future generations (Article 9). Consequently, the knowledge can only be licensed. The licence does not confer exclusive rights, nor is it able to prevent others from using the knowledge or other licences from being awarded on the same knowledge. Nor do the licences affect the right of the peoples to use and further develop their collective knowledge (Article 32).

The regime creates three instruments: a system to control *access* to the collective knowledge, a *system of registers* of collective knowledge, and an additional *funding system*, which is to contribute to the integral development of the indigenous peoples.

Access to TK is dependent upon obtaining the prior informed consent of the representative organizations of the indigenous peoples possessing the collective knowledge. Other indigenous peoples possessing the same knowledge are to be informed by the organization. Their interests and concerns are to be taken account of in the negotiations (Article 6). The law defines the obligatory contents of the licence contracts, such as information on the intended research, its risks and implications, the statement of the compensation and the obligation of the licensee to inform (Article 27). The contracts are to be registered by the National Intellectual Property Institute (INDECOPI, Instituto Nacional de Defensa de la Competencia y de la Protección de la Propiedad Intelectual), which verifies the legitimacy of the licence contracts. The conditions for gaining access are different for access for scientific and industrial use respectively. In respect of access for *scientific* use, only the prior informed *consent* of the people concerned is needed. In the case of access for *commercial* or *industrial* application, in addition, a licence contract has to be concluded. This contract has to fix the conditions for the payment for access and an equitable distribution of the benefits (Article 7). Further, the contract of licence must contain the obligation to periodically inform the licensor in general terms about the advances in the investigation, industrialization and marketing of the products

[87] Note 83 above.

[88] For the description of the legislation process, in particular in view of the participation of indigenous communities, see Tobin and Swiderska (2001).

developed from the collective knowledge (Article 21(e)).

The *Fund for the Development of Indigenous Peoples* is meant to support the comprehensive development of the indigenous peoples through the financing of projects and other activities (Article 37). The fund is autonomous and administered by an Administrative Committee which comprises five members of representative organizations of indigenous peoples and two members of the National Commission for the native peoples. The law states explicitly that the Committee shall, to the extent possible, proceed according to the traditional mechanisms and customs developed by the indigenous peoples for allocating and distributing collectively generated benefits.

The fund is made up of a percentage of the economic benefits resulting from the marketing of goods that have been developed on the basis of TK; further, of contributions from the state budget, international technical cooperation and donations (Article 41).

An interesting detail is that in cases where the collective knowledge has passed into the public domain within the previous 20 years, a percentage of the benefits resulting from the marketing of the goods developed on the basis of this knowledge has to be set aside for the fund. Collective knowledge is considered to be in the public domain either when it has been made accessible to persons other than the indigenous peoples by mass communication media, or where it has become extensively known outside the confines of the indigenous peoples and communities (Article 13). The Public Domain TK is registered in the Public National Register.

The registration system consists of three types of registers: the Public National Register, the Confidential National Register and the Local Registers (Article 15) (for details see Biber-Klemm, Chapter 7). The registers have a twofold purpose: on the one hand they are meant as instruments to preserve the collective knowledge of indigenous peoples; on the other hand they are intended to serve as a tool to defend the interests of indigenous peoples regarding their TK (Article 16).

The registration does not constitute rights over TK. All knowledge that is collective in nature, developed by indigenous peoples and which is not in the public domain, irrespective of whether it is registered or not, is protected against disclosure, acquisition or use without the consent of the indigenous peoples who possess it, and against unauthorized disclosure involving a breach of a duty of reserve. So there is a certain degree of protection but no exclusive rights are conferred (Article 42).

THE ANDEAN REGION'S EXPERIENCE IN PERSPECTIVE

The Andean Pact legislation on access to genetic resources and the Peruvian law on *sui generis* rights to TK have been hailed as landmarks in the process of implementing the CBD. In particular, the Peruvian legislation has been at the forefront for the creation of *sui generis* rights to TK associated with genetic resources. The Law 27811 provides a regulatory framework through which indigenous peoples can assert their rights over their collective knowledge (Ruiz Muller and Lapeña, undated, p. 15).

Yet, up to now, no access contracts have been concluded on the basis of Peru's TK legislation, and according to Ruiz, the Andean Pact Decision 391 has had little practical impact on the actual conclusion of access contracts (Ruiz Muller, 2003, para. No. 10).

Even if it may be too early to evaluate the Peruvian legislation, it might be interesting at this point to have a closer look at the possible reasons for this occurrence.

Ruiz Muller (2003) analyses the issue in view of the Andean Pact Decision 391. He identifies the creation of incentives as one of the most important factors to promote research into biodiversity. He considers it as an absolute necessity to create a legal framework that is clear, simple, practical, without inherent contradictions, and clearly promoting bioprospection.

He perceives the following as obstacles. First, the system of different layers of

contracts, given by the regime of differentiation in ownership described above. Secondly, the fact that the state is the principal negotiator, and, as a rule, has the lead in the negotiations in matters concerning scientific topics and technical and legal issues regarding genetic resources; in fact matters over which specialized institutes have greater capacity and expertise. Thirdly, the differences in access procedures for the different resources such as microorganisms, PGRFA and genetic resources for medicinal use; and finally, the high transaction costs (time, money, effort) the Decision generates, which might be higher than the expected benefits.

These observations, which in our opinion are also at least partly true for other countries and regions,[89] have led to a process aiming at evaluating and improving the regime in the near future (Ruiz, personal information). Ruiz advocates a proactive rather than a defensive approach to legislation in matters of ABS and pleads for a system that is simple, practical and flexible enough to be adapted to the variability of real access situations.

India[90]

India has made significant progress in recent years towards setting up a legal regime for the management of plant genetic resources. The proposed regime is laid out in three separate legislative instruments. These are: the Protection of Plant Varieties and Farmers' Rights Act, the Biodiversity Bill and the Patents (Amendment) Act of 2002. The separation of various elements into three is partly due to India's international legal obligations. The Plant Varieties Protection Act constitutes a response to Article 27.3(b) of the TRIPS Agreement,[91] the Biodiversity Act constitutes India's attempt to implement the CBD,[92] and the Patents (Amendment) Act seeks to put India in conformity with its TRIPS obligations in the field of patent protection.[93] The proposed regime reflects its fragmented parentage insofar as there are a number of inconsistencies or overlaps among the three bills. Since each instrument was drafted separately, they are examined in turn.

THE PLANT VARIETIES PROTECTION AND FARMERS' RIGHTS ACT

The Protection of Plant Varieties and Farmers' Rights Act constitutes the government's response to its obligations under Article 27.3(b) of the TRIPS Agreement. The Indian government has chosen not to introduce patents over plant varieties but rather to devise its own system of IPRs. Further, it was agreed that the UPOV Convention should not be ratified but that a law suited to the specific conditions of the country should be drafted. In its present form, the Act focuses on the establishment of plant breeders' rights and farmers' rights. The regime for plant breeders' rights largely follows the model provided by UPOV and the criteria for registration are the same as those found in UPOV, namely novelty, distinctness, uniformity and stability. The Act incorporates elements from the 1978 version of UPOV and includes some elements from the more stringent 1991 version, such as the possibility of registering essentially derived varieties.

The second main aim of the Act is to introduce farmers' rights. At this level, the Joint Parliamentary Committee, to which the bill was referred after its introduction in Parliament, has proposed substantial changes.[94] While the version of the bill originally introduced in Parliament only contained a short provision on farmers'

[89] See Biber-Klemm, ABS, Chapter 6 and Registration, Chapter 7.
[90] Author: Philippe Cullet.
[91] Protection of Plant Varieties and Farmers' Rights Act, 2001.
[92] Biological Diversity Act, 2002.
[93] Patents (Amendment) Act, 2002.
[94] See Joint Committee on the Protection of Plant Varieties and Farmers' Rights Bill, 1999, *Report of the Joint Committee* (August 2000).

rights, the Committee decided to add a whole new chapter on farmers' rights. As adopted, the Act seeks to put farmers' rights on a par with breeders' rights. It provides, for instance, that farmers, like commercial breeders, can apply to have a variety registered.[95] Generally, the Act envisages that farmers should be treated like commercial breeders and should receive the same kind of protection for the varieties they develop.

The Act also provides two avenues for benefit sharing.[96] The first scheme allows individuals or organizations to submit claims concerning the contribution they have made to the development of a protected variety. The final decision is taken by the Authority established under the Act, which determines the amount, taking into account the importance of the contribution in the overall development of the variety and its commercial potential. The second benefit-sharing avenue allows an individual or organization to file a claim on behalf of a village or local community. The claim relates to the contribution that the village or community has made to the evolution of a variety.

THE BIODIVERSITY ACT

The Biodiversity Act was drafted in response to the CBD. The Act does not aim at providing a general regime for biodiversity management but focuses on some specific elements that are of concern at present. The Act thus reflects the government's strong reaction to biopiracy.[97] The Act is also partly premised on the desire to avoid a direct confrontation with WTO obligations in the field of plant genetic resources.

Generally, the Act focuses on the question of access to resources.[98] Its response to the current challenges is to assert the country's sovereign rights over natural resources. It therefore proposes to put stringent limits on access to biological resources or related knowledge for all foreigners. The Act's insistence on sovereign rights reflects current attempts by various countries to assert control over national resources or knowledge. While the Act focuses on preserving India's interests *vis-à-vis* other states in rather strong terms, its main impact within the country will be to concentrate power in the hands of the government. Indeed, Indian citizens and legal persons must give prior intimation to the state biodiversity boards of their intention to obtain biological resources.[99] The Act is even more stringent in terms of IPRs since it requires that all inventors obtain the consent of the National Biodiversity Authority before applying for such rights.[100] The impacts of this clause are, however, likely to be limited since patent applications are covered by a separate clause.[101] Further, the Authority has no extra-territorial authority and cannot monitor applications for IPRs outside India.

Overall, the Biodiversity Act implicitly takes the position that India cannot do more than regulate access by foreigners to its knowledge base. It does, however, attempt to discipline the IPRs system in some respects. As noted, it requires inventors who want to apply for IPRs to seek the Authority's permission. It also authorizes

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[95] Section 16.1(d) of the Plant Varieties Act, note 94 above.

[96] See Sections 26 and 41 of the Plant Varieties Act, note 94 above.

[97] See, for example, US Patent No. 5,401,504, *Use of Turmeric in Wound Healing*, issued 28 March 1995 and European Patent No. EP 0436257, *Method for Controlling Fungi on Plants by the Aid of a Hydrophobic Extracted Neem Oil*.

[98] The only substantive chapter of the Biological Diversity Act – Chapter II – is entitled Regulation of Biological Diversity.

[99] Section 7 of the Biological Diversity Act, note 95 above.

[100] Section 6 of the Biological Diversity Act, note 95 above.

[101] Permission of the National Biodiversity Authority must be obtained before the sealing of the patent but can be obtained after the acceptance of the patent by the patent authority. See Section 6.1 of the Biological Diversity Act, note 95 above.

the Authority to allocate a monopoly right to more than one actor. Further, the Authority is also entitled to oppose the granting of IPRs outside India.[102] The Act also seeks to address the question of the rights of holders of local knowledge by setting up a system of benefit sharing. The benefit-sharing scheme is innovative insofar as it provides that the Authority can decide to grant joint ownership of a monopoly intellectual right to the inventor and the Authority or the actual contributors if they can be identified.[103] However, the sharing of IPRs is only one of the avenues that the Authority can choose to discharge its obligation to determine benefit sharing. Further, it is in the Authority's power to allocate rights to itself or to a contributor, such as a farmer contributor, and the latter has no right to demand the allocation of property rights. Other forms of benefit sharing include technology transfers, association of benefit claimers with research and development, or the location of production, research and development units in areas where this will facilitate better living standards for the benefit claimants.

PATENTS (AMENDMENT) ACT

The Patents Act adopted in 1970 dealt with patents in general and was not specifically related to biological resources. However, it addressed a number of issues that are of relevance in the context of PGR management. It rejected, for instance, the patentability of all methods of agriculture and was generally much more restrictive than similar laws in Western countries. TRIPS has imposed significant alterations to this Act. Thus, where formerly only a process patent could be obtained for no more than 7 years for food- or medicine-related inventions,[104] TRIPS now requires the availability of product and process patents for 20 years.

The Patents (Amendment) Act, 2002 generally seeks to modify the Act to allow compliance with TRIPS. There was not much scope for diverging from the rather precise TRIPS obligations if India wanted to avoid further confrontation with the WTO.[105] The Amendment Act thus brings the duration of the rights to a uniform 20-year period and also substantially modifies the sections concerning the working of the patents by, for instance, doing away with licences of rights. The provision that seeks to oblige patentees to manufacture their inventions in India was also struck out because of the TRIPS requirement that imports should not be treated differently from products produced locally.[106] With regard to environmental protection, the Amendment Act includes some of the TRIPS exceptions related to environment and health. It also addresses the question of biopiracy by imposing the disclosure of the source and geographical origin of biological material used in a patented invention. Further, non-disclosure of the geographical origin or the anticipation of the invention in local or indigenous knowledge constitutes grounds for opposing or revoking a patent.

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[102] Section 18.4 of the Biological Diversity Act, note 95 above.

[103] Section 21.2(a) of the Biological Diversity Act, note 95 above.

[104] Section 53 of the Indian Patents Act, 1970.

[105] India was taken to the WTO dispute settlement mechanism by both the USA and the EU for its failure to implement in due time its obligations relating to Exclusive Marketing Rights. For the US complaint, see, for example, India – Patent Protection for Pharmaceutical and Agricultural Chemical Products (US complaint), Report of the Panel, 5 September 1997, WTO Doc. WT/DS50/R, and India – Patent Protection for Pharmaceutical and Agricultural Chemical Products (US complaint), Report of the Appellate Body, 19 December 1997, WTO Doc. WT/DS50/AB/R.

[106] Article 27 of the Agreement on Trade-Related Aspects of Intellectual Property Rights, Marrakesh, 15 April 1994, reprinted in 33 ILM 1125 (1994).

2.4.2 Developed countries

Europe[107]

European states have sought harmonization of their intellectual property laws for a long time, both in the context of the European Union (EU) and in broader forums. The European Patent Convention (EPC) of 1973 currently brings together 27 states and provides a general framework for the harmonization of patent law throughout Europe.[108] It has become one of the focal points of interest in the development of patent law in the field of biotechnology. In the context of the EU, the most significant instrument with regard to recent developments in genetic engineering is undoubtedly the Biotechnology Directive of 1998.[109]

EUROPEAN PATENT CONVENTION

The EPC generally provides a uniform patent granting procedure that applies throughout the member states. In the context of the law of plant genetic resources, the EPC is particularly noteworthy with regard to the scope of patentability. The general conditions for patentability are substantially similar to those of the TRIPS Agreement and include the criteria of novelty, inventiveness and industrial applicability.[110] Some specific exceptions to patentability are provided in Article 53. This generally includes inventions whose exploitation would be contrary to public morality. The notion of public morality has been interpreted as covering public peace or social order or serious prejudice to the environment.[111]

The EPC also excludes the patentability of plant or animal varieties (but not plants and animals in general, as in the TRIPS agreement), or essentially biological processes for the production of plants or animals, with the exception of microbiological processes or their products that are patentable.[112] The exclusion from patentability of plant varieties was first interpreted by the European Patent Office (EPO) as being a consequence of the existence of national and international regulations for the protection of plant breeders' rights.[113] The consequence was that only the patenting of plants or their propagating material in the genetically fixed form of the plant variety was prohibited, but not the patentability of the plant or the animal itself. Since 1995, the interpretation of Article 53.b is that claims on plants are not acceptable because transgenic plants encompass plant varieties. However, plant cells have now been determined as being patentable.[114]

EUROPEAN UNION BIOTECHNOLOGY DIRECTIVE

The Directive on the Legal Protection of Biotechnological Inventions is now the central instrument in the EU context concerning the patentability of GMOs.[115] It has been one of the most contentious pieces of legislation to go through the European Parliament. After lengthy debates it was adopted in June 1998, and subsequently unsuccessfully challenged.[116]

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[107] Author: Philippe Cullet.

[108] Convention on the Grant of European Patents, Munich, 5 October 1973 (hereafter EPC).

[109] Directive 98/44/EC of the European Parliament and the Council of the European Union on the Legal Protection of Biotechnological Inventions, 6 July 1998, 1998 OJ L 213 (hereafter Biotechnology Directive).

[110] Article 52.1 of the EPC, note 111 above.

[111] *Plant Genetic Systems vs Greenpeace*, EPO Technical Board of Appeal, 21 February 1995 (T 356/93).

[112] Article 53.b of the EPC, note 111 above.

[113] Ciba-Geigy/Propagating Material, EPO Technical Board of Appeal, 26 July 1983 (T49/83), and Lubrizol/Hybrid Plants, 10 November 1988 (T 320/87).

[114] See *Plant Genetic Systems vs Greenpeace*, EPO Technical Board of Appeal, 21 February 1995 (T 356/93).

[115] Biotechnology Directive, note 112 above.

[116] See *Netherlands vs Council of the European Union*, Judgment of 9 October 2001 (Case C-377/98).

The Directive is premised on the recognition of the importance of biotechnology and the necessity of providing legal protection to biotechnological inventions in the European Community. It complies with other EU legal instruments and the EPC. The principle is that biotechnological inventions are to be protected by patent rights. It specifically excludes the patentability of plant and animal varieties, and essentially biological processes for the production of plants or animals. However, patentability is provided for inventions concerning plants or animals if the technical feasibility of the invention is not confined to a particular plant or animal variety. This significantly narrows down the exception concerning plant and animal varieties.

The Directive follows the EPC and TRIPS in prohibiting patentability in situations where the commercial exploitation of an invention would be contrary to *ordre public* or morality. It provides specific examples of inventions deemed to breach these norms. These include processes for cloning human beings and processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to human or animal, and also animals resulting from such processes.

The scope of protection provided under the Directive is extremely broad. A patent on biological material possessing specific characteristics gives the patent holder rights over any biological material derived from that biological material through propagation or multiplication in an identical or divergent form, and possessing those same characteristics. However, the Directive includes a limited exception in the case of agricultural use. It provides a form of farmers' privilege modelled after the plant breeders' rights model, authorizing farmers to use the product of their harvest for propagation or multiplication on their own farm.[117] This exception extends to protected livestock as well.

Finally, the question of the Directive's relationship with other international treaties in the field of patents and biodiversity must be highlighted. Article 1 specifically indicates that the provisions of the Directive are without prejudice to the obligations of the member states pursuant to international agreements, and in particular the TRIPS Agreement and the CBD. In its ruling on the application for annulment of the Directive brought by The Netherlands, the European Court of Justice had to give an opinion on the compatibility of the Directive with the CBD. In rejecting The Netherlands' contentions, the Court made an important statement concerning the theoretical impact of the Directive on the protection of TK. It stated that:

> [i]t cannot be assumed, in the absence of evidence, which is lacking in this case, that the mere protection of biotechnological inventions by patent would result, as is argued, in depriving developing countries of the ability to monitor their biological resources and to make use of their traditional knowledge, any more than it would result in promoting single-crop farming or in discouraging national and international efforts to preserve biodiversity.[118]

The Court further dismissed a claim concerning the absence of benefit-sharing provisions in the Directive. It noted that the CBD does not specifically impose on member states the obligation to take into account the interests of the country from which the genetic resources used in the patented invention originate. However, the Court also acknowledged that Article 1.2 imposes on member states the obligation to implement the Directive in such a way that they do not breach their obligations under the CBD.

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[117] See also Council Regulation (EC) No 2100/94 on Community Plant Variety Rights, 27 July 1994, OJ 1994 L227/1.

[118] C-377/98, note 119 above at § 65.

USA[119]

The USA has been at the forefront of the development of patent law, in particular in the fields of plant varieties and genetic engineering. The USA was the first country to enact a specific Plant Patent Act, in 1930, that provides protection for certain asexually reproduced plants.[120] Protection is granted to whoever invents or discovers and asexually reproduces distinct and new plant varieties. The scope of protection has been the subject of recent litigation. In *Imazio vs Dania*, the Court of Appeals determined that the term variety should be understood as providing protection only to a specific plant and not to a range of plants.[121]

The Plant Patent Act has been supplemented by the 1970 Plant Variety Protection Act, which grants protection to novel varieties of sexually reproduced plants.[122] The concept of variety is here informed by the definition found in UPOV-1991 and differs from the concept of variety found in the Plant Patent Act.[123] The rights granted under this Act are plant breeders' rights and not patents. One of the main differences between the two is that farmers can make use of seeds generated from protected stock, an exception that is not available under the patent regime. The scope of the exceptions in favour of farmers has been the object of significant debate. In *Asgrow vs Winterboer*, a seed company sued farmers for selling the crop produced from protected stock to other farmers for use as seed.[124] The main issue in this case concerned the scope of the farmer's privilege under 7 U.S.C. 2543. This section clearly protects farmers who use part of the seeds produced from protected stocks on their farm or who sell them. However, the court held that farmers are not protected in cases where the saved seed is grown for the purpose of sale for replanting because this constitutes a violation of 7 U.S.C. 2541(3).[125] The privilege under section 2543 is to be understood exclusively as authorizing a farmer to sell the seed s/he has set aside for the purpose of replanting his own acreage.

The lead of the USA in the context of plant variety protection has been extended in the past two decades to the field of genetic engineering. The USA was the first country to accept the patentability of artificially created life forms, thereby paving the way for the rapid development of the new biotechnology industry. The decision of the US Supreme Court in *Diamond vs Chakrabarty* triggered one of the most significant changes in the patent regime in recent times.[126] The Court was presented with the novel case of the 'invention' of an artificially created life form. It analysed the case from the point of view of the distinction between an invention and a discovery. In the balancing act, the Court put more weight on the fact that the bacterium was made by human beings (manufacture) than on the principle that products of nature did not constitute patentable subject matter under US law. The Court found support for its position in the existence of a plant patent Act that makes a clear distinction

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[119] Author: Philippe Cullet.

[120] Plant Patent Act of 1930, 35 U.S.C. 161 ff.

[121] *Imazio Nursery vs Dania Greenhouses*, 3 November 1995, Court of Appeals, Federal Circuit, 69 F.3d 1560.

[122] Plant Variety Protection Act of 1970, 7 U.S.C. 2321 ff.

[123] *Imazio Nursery vs Dania Greenhouses*, 3 November 1995, Court of Appeals, Federal Circuit, 69 F.3d 1560, 1568.

[124] *Asgrow Seed Company vs Denny Winterboer and Becky Winterboer*, dba Deebees, 18 January 1995, Supreme Court, 513 U.S. 179.

[125] 7 U.S.C. 2541: 'Except as otherwise provided in this subchapter, it shall be an infringement of the rights of the owner of a protected variety to perform without authority, any of the following acts (…): (3) sexually multiply, or propagate by a tuber or a part of a tuber, the variety as a step in marketing (for growing purposes) the variety'.

[126] *Diamond vs Chakrabarty*, 16 June 1980, Supreme Court, 447 U.S. 303.

between products of nature and human-made inventions rather than between living and inanimate things.

The 1980 decision left open the question of the patentability of plants and living organisms. In the 1985 decision *Ex parte* Hibberd, the patentability of plants was accepted.[127] After significant debates, the Patent and Trademark Office (PTO) granted in 1998 the first patent for a transgenic animal.[128] In the past decade, there has been a flurry of patent applications for transgenic plants and animals. Finally, in *J.E.M. vs Pioneer Hi-Bred*, the Supreme Court confirmed the possibility of inventors of new plant varieties applying for patents. The Court reasoned that the possibility of protecting new plant varieties under the Plant Variety Protection Act did not preclude protection through patents because the application conditions for the latter are more stringent and the rights granted more extensive. These developments must be understood in the context of further developments concerning the patentability of genes. In recent years, patents on genes that claim cover on an isolated gene, or constructs that include the gene, have been increasingly often admitted (Barton and Berger, 2001). This has a direct impact on transformed plants that include such constructs. In other words, the increasing scope of patentability in the field of plant variety must be understood not only with regard to patents on plant varieties themselves but also with regard to patents on genes that make up these varieties.

Australia[129]

FACTUAL BACKGROUND TO THE AUSTRALIAN POSITION

Megabiodiversity. Australia is a country – and continent – of tremendous biodiversity or 'megabiodiversity', holding about 13% of the world's biodiversity (Voumard, 2000, p. 7) and of the estimated 44,000 species of plants growing there, 88% are found only in Australia (Blakeney, 1997, 1999, p. 85). In terms of endemic species, Australia has the most mammals and reptiles, the second most birds, and fifth most higher plants and amphibians.[130]

> The isolation of the Australian continent has resulted in the survival of a number of simplified plant and animal types which have been particularly suitable for genetic modification, or which have provided a valuable reservoir of characteristics for the genetic modification of non-Australian plants and animals. For example, the aridity and salinity of the continent has resulted in the development of organisms with particular resistance to these conditions (Blakeney, 1999, p. 85).

The value of Australian indigenous traditional ecological knowledge and the problem of 'biopiracy'

Duboisia plant. The TK of Australian indigenous people about the properties of Australian plants has often been used in the commercialization of some of those plants,[131] but not always with adequate recognition of their contribution. For instance, the *Duboisia* plant, used by Queensland Aborigines for therapeutic purposes, was developed by a British surgeon at the end of the nineteenth century as a substitute for atropine, and later found to contain hyoscine, used as a sedative in

[127] *Ex parte* Hibberd *et al.*, 18 September 1985, Patent and Trademark Office Board of Patent Appeals and Interferences, 227 U.S.P.Q. 443.

[128] U.S. Patent No. 4,736,866, Transgenic Non-Human Mammals, 12 April 1988.

[129] Author: Danuta Szymura Berglas.

[130] Communication from Australia IP/C/W/310 2, October 2001 point 15.

[131] 'A recent examination of plant breeders' certificates issued by the Plant Breeders' Rights Office found that of 36 certificates issued over Australian native plants, 16 had traditional known uses. Two of these certificates issued to Australian Native Produce Industries Pty. Ltd. pertained to traditionally used food species: muntries, *Kunzea pumifera* (AU 96/031), and sea celery, *Apium prostratium* (AU 96/026). Allegedly, no breeding work had been carried out on these species' (Fourmile-Marrie, 1998, p. 2).

treating motion sickness and as a 'truth drug'. According to Blakeney, 'the cultivation of *Duboisia* is currently conducted on a commercial scale in Northern New South Wales and Southern Queensland, but without any recompense to indigenous peoples' (Blakeney, 1999, p. 86).

Native bush food. There is increasing interest in Aboriginal knowledge about bush food as a valuable source of nutrition. The Australian Native Bush Food Industry Committee reported that in 1996 bush food sales were over AU$14 million and rising (Woodley, 1998, p. 329, cited by Fourmile-Marrie, 1998, p. 2). In fact, a non-indigenous Australian, Les Hiddens, known as 'the Bush Tucker Man', has been very successful in bringing the value of Aboriginal knowledge about Australian bush food to the minds of all Australians, through his television programmes, books and CD-ROMs.[132] Unfortunately, this success has also led to him being condemned by some as 'the very public face of (biopiracy)' (Fourmile-Marrie, 1998, p. 2).[133] Apart from the question of whether indigenous Australians have been properly compensated for the commercialization of their TK remains the fundamental issue of whether they agreed to the commercialization of their knowledge by others in the first place.[134]

Acacias. Aboriginal knowledge about the food value of acacias was instrumental in a recent study conducted by the Australian Tree Seed Centre of the Commonwealth Scientific and Industrial Research Organization (CSIRO) Division of Forestry in several African dry-land countries (Senegal, Niger, Burkina Faso, Somalia, Kenya and Zimbabwe) upon the usefulness of planting acacias in those countries. 'With respect to food potential, what is currently known about the food value of acacias has been largely the result of tapping into Aboriginal knowledge' (Devitt, 1991). 'And yet', according to Fourmile-Marrie, 'Aboriginal people are not involved in the subsequent research, development and application processes regarding those overseas projects', contrary to Australia's obligations under the CBD (Fourmile-Marrie, 1998, p. 1).

Smokebush. The endemic plant smokebush (genus *Conospermum*) provides an interesting illustration (Janke, 1999, pp. 24–25). Smokebush grows in the coastal areas between Geraldton and Esperance in Western Australia, and its healing properties have been known and used by indigenous Australians for a long time. During the 1960s the Western Australian government granted the US National Cancer Institute (NCI) a licence to collect plants for screening purposes, and in 1981 specimens were tested for the presence of cancer-fighting properties. None were found, but the specimens were held in storage until the late 1980s when they were again tested, this time in the quest to find a cure for AIDS. Out of 7000 plants screened from around the world, Smokebush was one of only four plants found to contain the active constituent *conocurovone*, which laboratory tests showed could destroy low concentrations of the HIV virus. This 'discovery' was subsequently patented. The US National Cancer Institute has since awarded Amrad, a pharmaceutical company from Victoria,

[132] For instance, *Explore Wild Australia with the Bush Tucker Man* (1999) ABC Books/Viking, Sydney; CD-ROMs *From the Rainforest to Cape York* and *From Arnhem Land to the Kimberley*.

[133] For Aborigines, 'reproduction is unreal, while recreation is real. The fixation on the written word has implications for the practice of cultural heritage' (Janke, 1999, p. 7).

[134] Compare different points of view of indigenous Australians: Les Malzner stated at the Indigenous Reference Group Meeting, September 1997: 'Indigenous ownership is seen more in terms of responsibility for culture rather than excluding others from its use', whereas Francis Kelly Jupurrula, spokesperson for the Central Land Council submitted: 'We should keep it [knowledge of traditional medicines and bush tucker] for ourselves, not give it away. We are just like giving our land away altogether. I think we should all keep it because it's confidential … We should keep it for our generations' (speaking at Akarnenhe Well, 14–16 October 1997, CLC Submission January 1998) (Janke, 1999, pp. 44 and 46).

an exclusive worldwide licence to develop the patent.

In the early 1990s the Western Australian government also awarded Amrad rights to the smokebush plant in order to develop an anti-AIDS drug, having power to grant exclusive rights to Western Australian flora and forest species for research purposes pursuant to amendments made in 1985 to both the *Conservation and Land Management Act 1984 (Western Australia)* and the *National Parks and Wildlife Act (Western Australia)*. According to Blakeney (1997, p. 196), Amrad paid $1.5 million to the Government of Western Australia to secure access to smokebush and related species, based on projected royalties of $100 million per year by 2002 in the case of successful commercialization.

The concern of the indigenous Australians is that they have not received any acknowledgement, financial or otherwise, for their role in having first discovered the healing properties of smokebush. According to the Centre for Indigenous History and Arts (Western Australia):

> The current legislation disregards the potential intellectual property rights that the Indigenous peoples in Western Australia have in flora on their lands. Furthermore, multinational drug companies could be sold exclusive rights to entire species of flora, preventing anyone from using those species for any other purpose without the consent of the companies. Indigenous peoples in Western Australia now face the possibility of being prevented from using any of the flora which is the subject of an exclusive agreement. It is therefore vital that any reform of the intellectual and cultural property laws include provisions for the recognition of indigenous peoples as the native title owners of all the biological resources of the flora and fauna that are on their lands (Centre of Indigenous History and the Arts, submission to *Our Culture, Our Future*, October 1997 (Janke, 1999)).

In short, it is clear that indigenous Aboriginal ecological knowledge is valuable,[135] but a more just determination of the legal rights to Australia's biological resources and associated TK is still in the process of development.

ABORIGINAL INTELLECTUAL PROPERTY

Aboriginal acknowledgement of their IPRs. The *Julayinbul Statement on Indigenous Intellectual Property Rights* has expressly acknowledged the existence of 'Aboriginal intellectual property' which is found 'within Aboriginal Common Law', and as such 'is an inherent inalienable right which cannot be terminated, extinguished, or taken'.[136]

Clause 5 of the *Julayinbul Declaration*[137] includes 'the right [of indigenous people] to control subsequent use of and access to the genetic make-up within the flora and fauna of the forests'. Further, indigenous Australians would like to see the principle of prior informed consent, which applies to sovereign states under the CBD, to be extended to them (claim 7).[138]

The basis for the Aboriginal definition of their IPRs. Article 2(viii) of the Convention Establishing the World Intellectual Property Organization, 14 July 1967, defines *intellectual property* as the rights relating to literary,

[135] Although the value of indigenous knowledge to the biotechnology industry in Australia has not yet been estimated (Janke, 1999, p. 15).

[136] The Julayinbul Conference on Intellectual and Cultural Property, held at Jingarrba, in the Daintree Forest region of North-Eastern Australia on 27 November, 1993, produced the *Julayinbul Statement on Indigenous Intellectual Property Rights* and a *Declaration Reaffirming the Self-Determination and Intellectual Property Rights of the Indigenous Nations and Peoples of the Wet Tropics Rainforest Area*, cited by Blakeney (1999, pp. 93–95).

[137] *Declaration Reaffirming the Self-Determination and Intellectual Property Rights of the Indigenous Nations and Peoples of the Wet Tropics Rainforest Area*, produced by the Julayinbul Conference on Intellectual and Cultural Property, held at Jingarrba, in the Daintree Forest region of North-Eastern Australia on 27 November, 1993, cited by Blakeney (1999, pp. 93–95).

[138] See comprehensive list of indigenous claims in Janke (1999, pp. XX–XXI).

artistic and scientific works; performances of performing artists, phonograms and broadcasts; inventions in all fields of human endeavour; scientific discoveries; industrial designs; trademarks, service marks and commercial names and designations; protection against unfair competition; and all other rights resulting from *intellectual activity* in the industrial, scientific, literary or artistic fields (emphasis added).

The basis of this definition is 'intellectual activity', whether it stems from an indigenous or non-indigenous person, and TK – of both indigenous and non-indigenous people – is one form of intellectual activity within intellectual property.

The United Nations Special Rapporteur, Erica Irene Daes, stated in a 1993 report 'all elements of heritage should be managed and protected as a single, interrelated and integrated whole'.[139] According to the submissions made to the Australian Government by representatives of Aboriginal communities in their comprehensive report, *Our Culture, Our Future* (Janke, 1999), heritage forms the basis of any discussion on TK and IPRs held by Australian indigenous people. The report states that

> [indigenous] heritage consists of the tangible and intangible aspects of the whole body of cultural practices, resources, and knowledge systems developed, nurtured and refined by Indigenous people and passed on by them as part of expressing their cultural identity. (Janke, 1999, Chapter 1, p. 11)

This includes agricultural, scientific, medicinal and ecological knowledge, which are relevant in our context.

The report uses the term, 'indigenous cultural and intellectual property rights' to refer to indigenous Australians' rights to their heritage, adopting the terminology of Article 29 of the Draft Declaration of the Rights of Indigenous Peoples, 1994 (Janke, 1999, p. 7), which states that:

> Indigenous peoples are entitled to the recognition of the full ownership, control and protection of their cultural and intellectual property. They have the right to special measures to control, develop and protect their sciences, technologies and cultural manifestations, including human and other genetic resources, seeds, medicines, knowledge of the property of fauna and flora, oral traditions, literatures, designs and visual and performing arts.[140]

The explanation given by indigenous Australians for adopting 'indigenous cultural and intellectual property rights' rather than the World Intellectual Property Organization (WIPO) definition is to 'take into account the apparent distinction between "property", which suggests commercialisation and the protection of commercial rights, and "heritage", which implies preservation and maintenance issues' (Janke, 1999, p. 7). Further, the indigenous Australian definition intends to highlight the apparent distinction between the arts and culture on the one hand and science on the other, a split largely attributable to Western thinking.[141] It is not that 'property' and 'heritage' are mutually exclusive, but that heritage is another issue to consider.

> Traditional knowledge is regarded as common heritage and not as a commodity to be patented for commercial exploitation, perhaps to the exclusion of traditional owners. As with many other aspects of indigenous culture, knowledge of different plants and their healing properties is restricted to a particular class of people. Knowledge about the therapeutic

[139] *A Study on the Protection of the Cultural and Intellectual Property of Indigenous Peoples,* July 1993, E/CN.4/sub.2/1993/28,28 July 1993, para. 31, p. 9.

[140] Report of the Sub-Commission on Prevention of Discrimination and Protection of Minorities at its 46th session, *Draft United Nations Declaration on the Rights of Indigenous Peoples,* United Nations Documents E/CN.4/1995/2 and E/CN.4/Sub.2/1994/56.

[141] 'The development of specific legislation in the Australian framework has focused on arts and cultural expression only and has tended to neglect other areas of heritage, such as biodiversity knowledge, resources and scientific and medicinal application of cultural knowledge … This is because western culture tends to separate arts from science … in indigenous cultures, the division is less distinct' (Janke, 1999, p. 195).

> properties of plants is passed on by word of mouth. Indigenous people get access to such knowledge when they have attained the appropriate level of initiation. Just as practitioners of western medicine must study medicine before they can practise it, so a certain degree of knowledge is required before a plant can be used safely in indigenous society (Janke, 1999, p. 24).

Indigenous rights, like TK, are not something static, but subject to change. 'How will … [any reforms] meet the needs of artists who no longer belong to a traditional community, or whose communities can no longer say they own a particular design?' (Stephen Gray, unpublished, 1994). The same may be said for traditional ecological knowledge. 'Any legislation should not attempt to freeze Indigenous culture but should aim at allowing both so-called traditional and contemporary rights to be recognised and protected' (Janke, 1999, p. 186).

The communal nature of Aboriginal knowledge and resources. Australian Courts have recognized that classic intellectual property law is inadequate to deal with the communal nature of indigenous resources and TK.

In *Yumbulul vs Reserve Bank of Australia* (1991) 21 *Intellectual Property Reports* 481 (cited by Blakeney, 1999, pp. 91–92) the trial judge admitted that 'Australia's copyright law does not provide adequate recognition of Aboriginal community claims to regulate the reproduction and use of works which are essentially communal in origin' (p. 490). This case involved the reproduction by the Reserve Bank of the design of a Morning Star Pole on a commemorative banknote. The Galpu Clan of north-eastern Australia sought to prevent this on the basis of the communal obligation of the artist as a clan member to prevent the design of the pole being used in a culturally offensive manner – the authority and knowledge to use the design having been obtained through initiation and revelation – but the trial judge found that he had disposed of his IPRs in a legally binding document.

In *Milpurrurru vs Indofurn Pty. Ltd* (1995) 91–116 *CCH Australian Intellectual Property Cases* 39,051 (cited by Blakeney, 1999, pp. 91–92) the court was prepared to consider cultural harm in its assessment of damages for breach of copyright awarded to a number of Aboriginal artists whose designs were wrongfully reproduced on carpets. None the less, the idea of also compensating the communities of the artists who were no longer alive was rejected, for 'the statutory remedies [of Australia] do not recognise the infringement of ownership rights of the kind which reside under Aboriginal law in the traditional owners of the dreaming stories' (at 39,077). This is another example of Australian courts attempting to determine the extent to which Aboriginal customary law may be recognized under modern Australian law.

The problem is that in seeking to translate indigenous TK into modern intellectual property terms one has to deal with the Aborigines' notion of property, which is said to be 'quite different' (Janke, 1999, Chapter 5 and p. XXII). E.I. Daes has stated

> Indigenous peoples *do not view* their heritage in terms of property at all … but in terms of community and individual responsibility. *Possessing* a song, story or medical knowledge carries with it certain responsibilities to show respect to and maintain a reciprocal relationship with the human beings, animals, plants and places with which the song, story or medicine is connected. (Daes, 1993, emphasis added)

It is not that proprietary rights are rejected, but that they do not necessarily attach to any given individual, and in any case have certain communal responsibilities attached to them.[142] Aboriginal intellectual property includes the right to control the disclosure, dissemination, reproduction and recording of indigenous knowledge, ideas, and innovations concerning medicinal plants, biodiversity, and environmental management (claim 16)

[142] See list of indigenous claims in Janke (1999, pp. XX–XXI).

– which is similar to Western concepts – and *community* cultural and intellectual property rights (claim 5) – the communal element being foreign to Western notions of intellectual property, and so, not taken properly into account.

A related question is the role of the individual within the context of communal ownership. More correctly said it is 'a great number of generations *[of individuals]* [who] contribute to the development of indigenous cultural heritage'. In the case *Deceased Applicant vs Indofurn (1994) 30 Intellectual Property Reports 209 (the Carpets Case)* it was held that an individual or group is often the custodian or caretaker of a particular item of heritage. Artists may have the authority to depict a traditional, pre-existing design in their artwork by virtue of their birth or by initiation, but they hold this knowledge on trust for the rest of the clan. Further, sufficient evidence was found of individual artistic interpretation even though the artworks in question followed pre-existing traditional designs. The value of this case in our study is the exploration of the interrelationship between the individual and the community of which he or she forms a part, and the relationship between individual and community rights. This is fundamental to the discussion on how TK, which is mostly communal in nature, may be better integrated and protected by the largely individualistic system of Western intellectual property law.

Incidentally, the means of appointing one or more individuals as representatives of their clan is not problematic: *Bulun Bulun and Milpurrurru vs R. and T. Textiles Pty. Ltd.* Federal Court of Australia, unreported, 3 September 1998, van Dousa J. (WIPO, 2001, p. 71). In this way one or more community representatives of a defined indigenous or local community may advocate the rights of that community over its TK in much the same fashion as an individual would seek protection of his or her rights.

Public domain knowledge versus knowledge vested permanently with its holder. A problem is that, according to classical notions of intellectual property law, once ethnobiological information has been published, and patent or copyright protection has expired, it falls within the public domain (Blakeney, 1999, pp. 92–93; see Chapters 1 and 4, this volume), contrary to the customary law of indigenous people, who consider themselves the custodians of it in perpetuity. Indeed, 'the establishment of a public domain collecting society for indigenous works is not favoured because this supports the current legal assumption that indigenous cultural and intellectual property out of copyright is in the public domain and free for all to use and exploit' (Janke, 1999, pp. XXXIX and 208). Rather, an 'indigenous collecting society' is preferred, which recognizes the custodianship of indigenous and local communities over their TK in perpetuity.

For instance, the book *Bush Food* (Isaacs, 2000) provides a neat summary of the most important Australian biological resources known and used by Aboriginal Australians, compiled in collaboration with several indigenous Australians, who are photographed and named and arguably joint inventors for the purpose of the book itself. None the less, it was presumably not intended that this project would bring all the Aboriginal TK contained in the book within the classic public domain, even if the book was first published before the CBD. Indeed, the whole purpose of this type of book is to bring the value of indigenous knowledge to the attention of a wider audience – to educate others about the value of Aboriginal ethnobotanical and ethnobiological knowledge – but without in any way abrogating Aboriginal rights over it.

Henrietta Fourmile-Marrie states that 'a considerable amount of [Aboriginal] TK concerning [their] use of plant and animal species for food and medicine has already been published with the copyright to such information being held by non-indigenous collectors and institutions' (Fourmile-Marrie, 1998, p. 2). Examples include Cribb, A.B. and Cribb, J.W. (1974) *Wild Food in Australia*, Collins, Sydney; Cherikoff V.S. and Isaacs, J. (1989) *The*

Bush Food Handbook, Ti Tree Press, Balmain; Low, T. (1988) *Wild Food Plants of Australia*, Angus and Robertson, Sydney; Bindon, P. (1996) *Useful Bush Plants*, Western Australia Museum, Perth (note: only the last example is post-CBD).[143]

What is sought is that, first, the right as originator, custodian or holder of such knowledge be recognized; and secondly, that this right be used as a basis for claiming a right to compensation, which could take the form of some collecting society or communal fund, given the communal nature of indigenous TK. The use of registers to document important indigenous knowledge, with or without confidentiality, and perhaps despite prior publication, is another proposal (Janke, 1999, pp. 140, 229).[144]

AUSTRALIA'S OBLIGATIONS PURSUANT TO NATIONAL AND INTERNATIONAL LAW

The basis of the Australian legal system. Modern Australia is represented by about 200 years of European settlement, superimposed on an Aboriginal culture more than 60,000 years old. The basis is British and Australian common law, and the development of a modern democracy within a sophisticated social, economic, political and legal system.

The common law notion of *terra nullius*, in which the rights of Aborigines to their land were not recognized upon European settlement, was overturned in an important High Court decision, *Mabo vs Queensland (No. 2) 1992 (Commonwealth) 175 CLR 1*, which led to the enactment of the *Native Title Act 1993 (Commonwealth). Mabo* held that Aboriginal people and Torres Strait Islander ownership of land survived the colonization of Australia, and recognized a form of property called 'native title' which 'has its origin in and is given its context by the traditional laws acknowledged by and the traditional customs observed by the indigenous inhabitants of a territory' (Justice Brennan in *Mabo vs Queensland*, p. 58; WIPO, 2001, p. 78). This has helped to pave the way for indigenous customs to be recognized by modern law, which is an ongoing process.

National and international legal obligations. Australia is party to numerous international conventions, and is at the forefront in developing legislation to take better account of the special needs of its indigenous people. Work is being done on two levels: the further development of modern law, and the coordination of indigenous rights and responsibilities within that modern law. Australia has developed a draft legislative model for regulating access to genetic resources, and considers existing legal and administrative mechanisms as the most appropriate basis for the protection of TK (Communication from Australia IP/C/W/310 2 October 2001 point 1).

Australia ratified the CBD on 18 June 1993, and is party to TRIPS and the International Treaty on Plant Genetic Resources for Food and Agriculture. The *Plant breeders' rights Act 1994 (Commonwealth)*[145] gives effect to Australia's obligations as contracting party to the 1991 text of the International Convention for the Protection of New Varieties of Plants, known as the UPOV Convention, which Australia joined as a Member on 1 March 1989 and ratified on 20 January 2000. Section 17 of the Act recognizes the 'farmers' privilege', allowing seeds to be saved for replanting.

Further, there is an abundance of Com-

[143] Some indigenous Australians believe that indigenous people should receive compensation for aspects of culture that were applied commercially in the past (Janke, 1999, p. 15).

[144] 'Consideration should be given to the establishment of a national register which identifies the owners of ICIP. Any established register should not be a means of evidencing title. The register should only be used to provide contract details for subsequent users of indigenous material to contact the relevant community for prior consent. The register should be designed, managed and controlled by indigenous people' (Janke, p. XLI and Chapter 22).

[145] The *Plant breeders' rights Amendment Bill 2002 (Commonwealth)* seeks to clarify the rights of plant breeders to remuneration regarding public interest restriction and enhance the access of plant breeders to the Plant breeders' rights Scheme (Bills Digest No. 164 2001–02).

monwealth, State and Territory legislation and policy recommendations relating to this topic.[146] Section 51(xviii) of the Australian Constitution gives the Commonwealth, meaning Federal Government, the power to make special laws regarding copyright, patents or inventions and designs, and trade marks, and the common law provides the remedies of breach of confidence and passing off. Under Australian law, State and Territory governments (corresponding with *Canton* level) are primarily responsible for access to genetic resources found in non-Commonwealth land and waters, but it becomes a Commonwealth concern to the extent that federal matters become involved, such as trade and commerce, corporations, external affairs, export control and laws for the 'people of any race'. In any case, the State and Territory governments are similarly bound by Australia's obligations under the CBD pursuant to the external affairs clause in the Federal Constitution (Fourmile-Marrie, 1998, p. 5).

Recommended Action 6.1.7 of the *National Strategy for the Conservation of Australia's Biological Diversity* (an instrument of public administrative law) proposes that within Australia one ought to:

> Recognise the value of the traditional knowledge and practices of Aboriginal people and Torres Strait Islanders and integrate this knowledge and those practices into biological diversity research and conservation programmes by:
>
> Encouraging the recording (with the approval and involvement of the indigenous people concerned) of traditional knowledge and practices;
>
> Assessing their potential value for nutritional and medicinal purposes, wildlife and protected management and other purposes; and
>
> Applying traditional knowledge and practices in ways which ensure the equitable sharing of the benefits arising from their use (National Strategy, 1992, p. 4, cited by Blakeney, 1989, p. 89).

In the Report, *Biodiversity. The Role of Protected Areas* (1993), the House of Representatives Standing Committee on Environment, Recreation and the Arts commented that the identification of traditional practices entails more than the gathering of information, as it raises 'questions of authenticity, knowledge and power'. The Committee recommended that Action 6.1.7 be amended so that indigenous communities are encouraged 'to undertake or otherwise collaborate in research projects which utilise TK and practices in the study of biodiversity and in conservation' (paras. 4.70 and 4.72).[147]

On ABS: The Environment Protection and Biodiversity Conservation (EPBC) Act 1999 (Commonwealth). The EPBC Act 1999 replaces the National Parks and Wildlife Conservation Act 1975 (Commonwealth), but does not affect operation of the Native Title Act 1993 (Commonwealth), which is discussed below.

S301 of the EPBC Act 1999 provides the mechanism to implement Australia's international and domestic obligations for the control of access to biological resources in Commonwealth areas:

1. The regulations may provide for the control and use of access to biological resources in Commonwealth areas.
2. Without limiting subsection 1, the regulations may contain provisions about all or any of the following:
(a) the equitable sharing of the benefits arising from the use of biological resources in Commonwealth areas;
(b) the facilitation of access to such resources;
(c) the right to deny access to such resources; and

[146] *Designs Act 1906; Copyright Act 1968; Circuit Layouts Act 1989; Patents Act 1990; Trade Marks Act 1995; Plant Breeders Rights Act 1994 (*and *Plant breeders' rights Amendment Bill 2002).*
[147] Also see the discussion paper entitled *Access to Australia's Biological Resources*, prepared by the Coordination Committee on Science and Technology (CCST), Department of the Prime Minister and Cabinet, Office of the Chief Scientist, AGPS, Canberra, March 1994, pp. 31–32, cited by Blakeney (1999, pp. 89–91).

(d) the granting of access to such resources and the terms and conditions of such access.

In 2000 a Commonwealth Public Inquiry over access to biological resources in Commonwealth areas advised upon a scheme with legal effect that could be implemented through regulations under s. 301 of the EPBC Act 1999 (Voumard, 2000). In essence, the scheme seeks to implement the CBD goals of the conservation and sustainable use of biological resources and the equitable sharing of its benefits, together with the protection of TK, especially that held by indigenous people.

Specifically, the scheme provides for an access permit to native biological resources found in Commonwealth areas, which may be granted or refused by the Government in consultation with the relevant Government Agency or landowner, depending on whether the collection of materials would be ecologically sustainable; and a benefit-sharing contract based on a model contract developed and agreed upon by governments, industry, indigenous organizations and other stakeholders. The benefit-sharing contract between the parties must address prior informed consent, mutually agreed terms, adequate sharing of any benefits derived and the value and protection of indigenous knowledge and environmental benefits in the area from which the resource was obtained.

Applications for Access Permits may be made on-line; the Application fee may only be 'moderate'; and 'as far as possible (subject to concerns about confidentiality), information about access and benefit sharing agreements would be made public' (A Guide to the Draft Amendments to the Environment Protection and Biodiversity Conservation Regulations, 2000 – Access Permits and Benefit Sharing Arrangements, cited in Communication from Australia). The Minister may attach conditions to the Access Permit, such as the obligation to lodge voucher specimens in Australian public collection institutions, or the provision of information about the specimens.

Interestingly, the decision of the traditional owners of biological resources to deny access to their resources is explicitly not reviewable (Voumard, 2000, pp. viii and 21). This is in order to prevent 'legal bullying' which may wear down their decision to deny access, but conceivably could be a problem if the denial of access conflicts with Australia's obligations to provide access for 'environmentally sound uses' pursuant to the CBD.

Where biological resources are in a Commonwealth reserve that is not Commonwealth-owned land, such as Uluru-Kata Tjura (Ayers Rock), Booderee National Parks (Jervis Bay) and parts of Kakadu National Park, the rights of the land owner as owner of biological resources may be regulated by the EPBC Act or regulations made under the Act in relation to Commonwealth reserves (Voumard, 2000, pp. 47, 68 and 71). As Commonwealth 'areas' under s. 525 of the EPBC Act, they are owned by indigenous Australians and administered by Environment Australia under certain leasing arrangements. For example, s. 354 (1) (a) requires that a sample of a native species be taken in accordance with a management plan for the reserve, but this would not affect the exercise of 'traditional' rights to use Aboriginal land in accordance with the *Aboriginal Land Rights (Northern Territory) Act 1976* (s. 71), or native title rights in accordance with the *Native Title Act 1993*. Section 8(2) of the EPBC Act 1999 provides that the EPBC Act does not affect the operation of those Acts.

In short, after determining who owns or who is primarily responsible for the (Commonwealth) land upon which the biological resources may be found, the ABS provisions of the EPBC Act come into play, which themselves do not abrogate the inherent indigenous rights over that land and its resources as recognized by the Native Title Act.

On land rights: The Native Title Act 1993 and Native Title (Amendment) Act 1998 (Commonwealth). The *Native Title Act 1993 (Commonwealth)*, which arose in response to the *Mabo* decision mentioned earlier, preserves native land title and associated

rights from confiscation by the government.

The issue of land rights is clearly of central concern to local and indigenous communities as custodians of their biological resources and related TK. The connection between TK and land rights is recognized in Section 223(1) of the Native Title Act, which defines 'native title' as 'the communal, group or individual rights and interests of Aboriginal peoples or Torres Strait Islanders in relation to land or waters' provided that three conditions are fulfilled:

1. The rights and interests must be possessed under the traditional laws acknowledged and customs observed by the Aboriginal and Torres Strait Islanders.
2. The Aboriginal or Torres Strait Islanders must, by those laws and customs, have a connection with the land and waters.
3. The rights and interests must be recognized by the common law of Australia, being the most difficult condition to prove amongst these three (Blakeney, 1999, p. 95).[148]

Section 223(2) refers to 'hunting, gathering or fishing rights and interests' as being included within Native Title, and has been interpreted as meaning that, first, others are not excluded from also exercising these rights, and secondly, that even where traditional medical remedies might have become the subject of a patent or plant variety registration, Aboriginal people would still be permitted to continue to use such traditional medical remedies (Blakeney, 1999, p. 87).

Furthermore, according to current Australian legal opinion, native title rights can include the right to access and use of biological resources, and to control the right of others to access and use of biological resources in relation to particular land, including a corresponding denial of access, but native title would not (yet) encompass a right to control *all uses of a resource wherever it was located* (emphasis added) (Voumard, 2000, p. 72). The Aboriginal custodians of a plant found on *their* land would not be able to extend their rights to the *same plant* found growing on *someone else's* land. Each case of who owns or is primarily responsible for specific land, upon which certain biological resources are found, must be considered individually. This is a practical approach, reflecting the attempt in Australia to take into account competing claims based upon different systems of law, meaning both the rights found under modern Australian law and indigenous customary law.

An important element of modern Australian bioprospecting agreements[149] is that they are made with both the relevant State government and indigenous authorities, and that the benefits are shared with the Aborigines as custodians of the biological resources.[150] For instance, Section 14 of the Kakadu National Park Management Plan[151] reserves the right of the traditional owners, the Bininj/Mungguy, to continue to exercise their traditional rights to gather plants and plant material for food and for making cultural artefacts.

The Uluru-Kata Tjuta National Park Management Plan provides that in respect

[148] *Mabo* was confirmed in the recent High Court decisions of *Western Australia vs Ward; Attorney-General (Northern Territory) vs Ward; Ningarmara vs Northern Territory [2002] HCA 28 (8 August 2002)* found at http://www.austlii.edu.au/au/cases/cth/high_ct/2002/28.html, and *Members of the Yorta Yorta Aboriginal Community vs Victoria and Others* (M128/2001) http://www.austlii.edu.au, which was also mentioned in the *Neue Zürcher Zeitung*, 17 December 2002, p. 52.

[149] For instance, ExGenix Ltd (formerly Amrad Discovery Technologies) has agreed to this (Voumard, 2000, pp. 94–95).

[150] Although the CSIRO submitted to a Canberra Hearing on 30 May 2000 that the intrinsic value of biological resources and associated traditional knowledge can be quite limited. The Queensland government commented that the chance of discovering a new pharmaceutical may be 1 in 1,000,000 samples screened, costing about AU$100 million, taking 8–15 years to develop. The possible monetary benefits from bioprospecting agreements are often overestimated (Voumard, 2000, p. 99).

[151] This has legal effect according to principles of Administrative Law.

of bioprospecting agreements,[152] the agreements need not be exclusive; the indigenous owners may continue to use their resources and knowledge; the indigenous owners may not be forced to divulge their knowledge; and ABS may be determined in accordance with traditional laws and customs (Voumard, 2000, Chapter 6).

The significance of these examples is to show how rights to traditional genetic resources and related TK may be given legal recognition through the existing legal system (Communication from Australia point 29).

The inextricable link between rights over biological resources and TK, including ABS, and rights to land. Perhaps the real difficulty is not to devise an ABS scheme for biological resources in Commonwealth areas, or even to recognize the rights of indigenous Australians to their TK and resources, but to identify the true holder of the resources where competing claims are made over them. 'Commonwealth areas' refers by definition to Commonwealth waters and land owned or leased by the Commonwealth and Commonwealth Agencies, and land in external territories, which may conflict with indigenous claims pursuant to their customary law. The central issues in litigation have become: who has control over the land upon which the biological resources may be found? Are such land rights exclusive? And can they be suspended or extinguished? This conflict reflects the competing claims made by the interaction of modern law with indigenous law. For instance, the *Commonwealth Aboriginal Land Rights (Northern Territory) Act 1976* deals with agreements made between the Northern Territory Government and the Aboriginal people to the effect that the communities own the land, and in some cases lease it back to the government. Occasionally there are disputes between the Aboriginal people and the State or Territory government over who owns the biological resources or minerals found there (WIPO, 2001, p. 78 citing Roundtable, Darwin, Australia, 15 June 1998, Northern Land Council Darwin).

Milirrpum vs Nabalco (1971) 17 FLR 141 recognized Aboriginal customary law as a 'system of law' within the Australian legal system. The fundamental connection which Aborigines have with their land is spiritual (per Blackburn, J. at 167), but neither spiritual connection nor cultural knowledge alone is sufficient to constitute native title to land, which also requires a physical presence on the land {s. 223 (1) (b) of the Native Title Act; *Western Australia vs Ward; Attorney-General (NT) vs Ward; Ningarmara vs Northern Territory (Ward's case)* [2002] HCA (8 August 2002) (Full Court of the High Court of Australia) para. [964.6] and [964.8] per Callinen J.}. Abandonment of traditional lifestyle was found to sever the connection of the Yorta Yorta people to certain land in the case of *Members of the Yorta Yorta Aboriginal Community vs Victoria and Others* (M128/2001), although this decision is not considered final.

Ward's case involved different land tenure including vacant Crown land, pastoral leases, Crown land in or about the town of Kununurra, the Ord River irrigation area, Lake Argyle and the Argyle Diamond Project and the Keep River National Park, and certain waters. Even if native title is found to exist, it may be partially or wholly suspended or permanently extinguished[153] by such things as the granting of pastoral leases or mining leases and the resumption of land for the carrying on of public works: [453], [454], [468.3] and [468.4]. Pastoral leases may provide exclusive possession with a reservation in favour of Aborigines to enter and enjoy, for subsistence purposes. 'To the extent that rights and interests granted by the pastoral lease were not inconsistent with native title rights and interests, the rights and interests under the

[152] Major companies involved in bioprospecting in Australia include AstraZeneca, ExGenix (formerly AMRAD), Australian Institute of Marine Science, CSIRO and BioProspect Limited (Voumard, 2000, p. 93).
[153] Under s 237A 'extinguishment' of native title is permanent, otherwise it is a mere suspension of rights that may be revived.

lease prevailed over, but did not extinguish, native title rights' [464] and [468.10]. Conversely, if exclusive possession is validly granted then there is no need to consider inconsistency, because by definition, exclusive possession is inconsistent with native title: per Callinen J. [964.3]. A lease granted for a national park may protect traditional Aborigine use of the land where native title is not wholly extinguished.

A lease granted in perpetuity may give the lessee a right of exclusive possession that extinguishes all native title: *Wilson vs Anderson* [2002] HCA 29 8/08/02. Aborigines may in some cases simply have the right of occupation to live on the land and seek their subsistence from it – like a lodger in a house owned and exclusively possessed by another (*Ward* [555]).

Ward held that '[t]he evidence established no native title right to or interest in any mineral or petroleum. [So] no question of extinguishment arises' (*Ward* [482] and [468.22]), although this view was not shared by Kirby J.

The common law recognizes the concept of joint possession. 'But possession that is not exclusive is a contradiction in terms, for the right of general control and exclusion is central to the concept of legal possession' [477]. In a similar case, *Wik Peoples vs Queensland* (1996) 187 CLR 1, the pastoral leases were not thought to confer exclusive possession or else did not necessarily extinguish native title, a controversial result which will be limited to its facts [473–481].

The attempt to integrate Australian indigenous law into the modern common law legal system is regarded sceptically by some. In *Ward's* case, His Honour Callinen J. remarked that it would probably be better to 'redress the wrongs of dispossession by a true and unqualified settlement of lands or money than by an ultimately futile or unsatisfactory, in my respectful opinion, attempt to fold native title rights into the common law' ([970] and [1064]). The Commonwealth Regulations would in any event not alter existing property law in Australia.

His Honour's point was that:

> this Court and other legal bodies are founded on a post-dream time legal order. Although some may contend that we should, we do not in fact recognise Aboriginal criminal law, tort law or any aspects of indigenous laws, nor do we pretend to. The question then is why the common law of property, which had been regarded as settled for more than a century, should have been changed to recognise sui generis interests in land that had no counterpart in our legal system. [1064]

This raises the issue of the compatibility – or incompatibility – of maintaining 'two equal and parallel systems of law', an issue raised by indigenous Australians in Janke (1999).

HOW WOULD ABORIGINAL SUBMISSIONS FIT IN WITH THE EXISTING AUSTRALIAN LAW?

To what extent can 'Aboriginal intellectual property' and 'Aboriginal common law' be reconciled with Western notions of intellectual property law and with modern Australian law in particular? Consideration of certain statements and reports reveals a fundamental division of opinion about certain key issues.

The Final Statement of the South Pacific Regional Consultation on Indigenous Peoples' Knowledge and Intellectual Property Rights, held in Suva, Fiji, in April 1995, in which indigenous Australians took part, accuses the modern IPR system and modern science and technology of 'perpetuat[ing] imperialism … to control and exploit the lands, territories and resources of indigenous peoples'. This is clearly a rejection of the Western form of IPRs, though not a rejection of IPRs *per se*. None the less, such thinking led to a call for the Pacific Region to be 'a life forms patent-free zone' (Article 1), and 'a moratorium on bioprospecting in the Pacific' (Article 2), at least until 'appropriate protection mechanisms are in place' (Blakeney, 1999, p. 94). What is alarming is the result that research and investment in natural biological resources will thereby be discouraged, and the motivation to cultivate such resources may be so reduced as to bring them

into danger of extinction (see Chapter 1 on loss of biological resources and related TK). The Final Statement also declared 'the right of indigenous peoples of the Pacific to self-governance and independence of our lands, territories and resources as the basis for the preservation of indigenous peoples' knowledge', the wider ramifications of which fall outside the scope of this study.

On Access and Benefit Sharing. Indigenous Australians consider there to be 'some things that cannot be sold, such as secret/sacred objects and information', and 'indigenous people should be able to stop commodification of certain aspects of their cultures' (Janke, 1999, p. XIX). In short, they demand the right to control access over their knowledge and resources.

Otherwise, indigenous Australians may be interested in benefiting from the commercialization of some of their knowledge and resources.[154] The difficulty is assessing the worth of the contribution of TK to an invention based upon it.

Blakeney notes that 'it will often be questionable whether the contribution of indigenous knowledge from which a pharmaceutical product is developed can be considered to be the sort of contribution which will allow the indigenous persons to be considered a joint inventor under patents law' (1999, p. 93). This is because merely 'being the first to observe a useful property or effect of an invention' (*Consolidated Aluminum Corp. vs Foseco Int'l Ltd* 10 U.S.P.Q. 2d 1143) does not amount to joint inventorship, which requires each joint inventor 'working toward the same end and producing an invention by their aggregate efforts' [269 F. Supp. 818 (DDC1967)].

Alternatively, where ethnobiologists work together with local or indigenous communities in order to discover both the identity of medicinal plants and the treatments for which they are used, the contribution of TK to the development of a plant-based drug is more evident, and accordingly, the demand for a fair share of the profits is greater (Blakeney, 1999, p. 93).

In fact, a distinction exists between the traditional use of a plant, known for its healing purposes, which is or which ought to remain unaffected, and patent protection on new inventions stemming from that plant, such inventions falling outside the scope of TK. Confusion about this is detrimental to the discussion on the apportionment of the benefits derived from the use of the plant and the TK related to it.

At any rate,

> what is becoming evident … is that Nature is probably not going to produce the next 'blockbuster drug' directly, but that the chemical structures that Mother Nature provides are the structural leads that chemists will then modify to produce 'improved molecules' that no chemist in his or her right mind would have considered making de novo. (Sub. 39 of a CSIRO report cited in Voumard, 2000, p. 237; also consider the Smokebush example mentioned earlier)

That being so, a case can still be made for compensating indigenous people to the extent that they point chemists in the right direction of the benefits that 'Mother Nature' has to offer.

The integration of modern law and indigenous law. Australian legal thinking on the legal rights to plant genetic resources and related TK, especially that which is held by indigenous Australians, is in a process of evolution and compromise.

Some indigenous Australians would like to see the implementation of 'two parallel and equal systems of law' within Australia (Janke, 1999, Part Three of the Report and p. XXVII). Although there is a certain attractiveness to this idea – recognizing indigenous customs to have equal merit – the notion is rejected for both practical and conceptual reasons (Communication from

[154] Claim 9 in the list of indigenous claims (Janke, 1999, pp. XX–XXI). For example, the Aboriginals of Uluru, formerly known as Ayers Rock, now keep part of the proceeds collected from tourists, in recognition of their custodianship.

Australia points 24–32; 31). First and foremost, it is not possible for any state to pursue two separate systems of law and government simultaneously. Either the notions espoused by indigenous law will be compatible with those found in modern law, in which case such law is superfluous, or else they will conflict, in which case an order of priority will need to be determined. This must take into account not only subjective notions of which law is preferable, but also the correct political and legal means to effect changes in the law, which is, after all, the law of the land, in this case a constitutional democracy for all of its citizens whether indigenous or not.

The common law view is that the sources of law are to be found in an increasing order of importance, and that customary law is already included as a source of law, although legislation and case law take precedence over it (see any standard legal text such as *Legal Institutions* by Professor William Morison, Law Book Company, Sydney). 'Specifically, Australia assesses the existing legal framework, and then seeks to apply practical measures that accommodate indigenous concerns in the day to day management and administration of ICIP' (Communication from Australia point 25). 'An entirely new form of statutory protection for ICIP, as envisaged by the Report Our Culture, Our Future is seen by the Australian government to be a "dramatic step", introducing a level of unnecessary complexity and duplication which the government would rather avoid in favour of developing the existing legal system' (Communication from Australia point 31). The Australian government also uses 'non-legislative means … to accommodate indigenous concerns in the daily management of intellectual and cultural property' (point 32), including collecting societies (point 33).

If 'two equal and parallel systems of law' are strictly not possible, what, then, is possible? A number of decisions[155] and developments have led to the suggestion that 'Aboriginal and Torres Strait Islander IPRs may be recognisable by Australian law either as part of native title within the scope of the reasoning in the Mabo decision, or by analogy with it' (Gray, 1998, p. 78).

Aboriginal Australians have in turn recommended that a *sui generis* legislative framework be established to protect indigenous cultural and intellectual property rights, including ecological knowledge, and that 'any rights granted should ensure that there are no time limits on protection and no fixed form requirement for protection to be given' (Janke, 1999, p. XXXVI).

Further, 'the legislation should not inhibit the further cultural development of materials within their originating communities. That is, customary and traditional use should not be affected' (Janke, 1999, p. XXXVI).

CONCLUSIONS

The development by Australia of a Model Contract on Access and Benefit Sharing is a valuable contribution 'to the global community … [on] this important issue' (Communication from Australia point 18). 'It is hoped that the measures taken by Australia to protect indigenous intellectual and cultural property within Australia may be of use to other countries' (point 22).

Clearly, in order to incorporate concepts of Aboriginal intellectual property into modern Australian law it is necessary to think of intellectual property as something more than the protection of commercial interests for a given period only. There must be a more fundamental recognition of the worth of all intellectual activity, whether stemming from indigenous or non-indigenous people. In this way, intellectual property may be considered to be part of cultural heritage, rather than something incompatible with it.[156]

[155] *Native Title Act (1993) (Commonwealth)* – which arose due to *Mabo; Wik Peoples vs State of Queensland* (1996) 141 ALR 129; *Bulun Bulun vs Nejlam Pty. Ltd.* (1989) Federal Court of Australia; *Yumbulul vs Reserve Bank of Australia* (1991) 21 IPR 481; and *Milpurrurru vs Infofurn Pty. Ltd.* (1995) 30 IPR 209.

[156] This was suggested by the Office of National Tourism in their submission to *Our Culture, Our Future,* 1997 (Janke, 1999, p. 8).

Furthermore, any effective system for protecting the legal rights over biological resources and related TK must also address the issue of rights over the land in which they are found. There are features of indigenous ecological knowledge that are worthy of special attention, and Australia is at the forefront of attempting to integrate indigenous customary law into the modern legal system. It may be said that Australia is an interesting example of the process of bringing together both North and South interests.

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