

**ARTICLE 27.3(B), RELATIONSHIP BETWEEN THE TRIPS AGREEMENT
AND THE CBD AND PROTECTION OF TRADITIONAL KNOWLEDGE
AND FOLKLORE**

Communication from Peru

The following communication, dated 2 June 2005, is being circulated at the request of the delegation of Peru.

**Biodiversity, Traditional Knowledge and Intellectual Property: Peru's Position
in Relation to Disclosure of Origin and Legal Provenance**

I. EXECUTIVE SUMMARY

The most controversial issue in international discussions on the relationship between biodiversity, traditional knowledge and intellectual property at the present time is the political and legal viability of requirements concerning disclosure of origin and legal provenance of genetic resources or traditional knowledge.¹

Countries are divided between those that oppose the inclusion of this type of requirement in the patent system (at international or national level) represented by the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) of the World Trade Organization (WTO), those that are considering the possibility of such inclusion, albeit on a voluntary basis and one that is limited (to disclosure of origin) and those others, including Peru, which advocate mandatory inclusion so as to guarantee the more efficient and secure implementation of TRIPS itself and generate a situation of positive synergy between TRIPS and the Convention on Biological Diversity (CBD).²

¹ The world's foremost specialists on intellectual property have agreed that the requirements for disclosure of origin (also referred to as "disclosure of origin or source") and legal provenance do not conflict with the TRIPS obligations. See for example the report: Memorandum prepared by Joshua Sarnoff del Glushko – Samuelson Intellectual Property Clinic, Washington University College of Law, American University. Compatibility with Existing International Intellectual Property Agreements of Requirements for Patent Applicants to Disclose Origins of Genetic Resources and Traditional Knowledge and Evidence of Legal Access and Benefit Sharing (June 2004). This document was commissioned by the Public Interest Intellectual Property Advisors, Inc. It is important to point out that the concept of legal provenance presupposes the existence of prior informed consent (PIC) and of fair and equitable benefit-sharing.

² An important milestone in the WTO context is the Doha Declaration (adopted on 14 November 2001 at the Fourth WTO Ministerial Conference), in paragraph 19 of which Ministers agree to 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*

One of the main concerns of Peru and various other countries (including the Group of Like-Minded Megadiverse Countries)³ is the fact that the patent system, as currently operated, frequently gives rise to situations in which inventions based directly or indirectly on genetic resources of Peruvian origin or the traditional knowledge of Peruvian communities pass the novelty or inventiveness tests when they should not do so or, alternatively, that these resources or knowledge could have been obtained in an unauthorized or patently illegal manner.

These circumstances do much to undermine the functioning of the patent system itself and have a direct effect on the interests of the countries concerned with regard to both the fulfilment of international obligations under the CBD and the establishment of levels of complementarity between that international instrument and the TRIPS Agreement.

As part of a lengthy process initiated in the early 1990s, Peru has consistently maintained its position on disclosure and legal provenance in the different intergovernmental negotiating forums where the subject has been addressed, i.e. the CBD itself, the WTO and the World Intellectual Property Organization (WIPO). Accordingly, Peru deems it necessary:

- (a) To establish an international obligation under the TRIPS Agreement (as well as another binding international instrument, possibly including the WIPO Patent Law Treaty or the Substantive Patent Law Treaty) so as to require the disclosure, under the mechanism for evaluating patent applications, of the geographical and legal provenance of genetic resources or traditional knowledge that could form part (directly or indirectly) of an invention;
- (b) to establish penalties for non-compliance with this requirement in those instruments; and
- (c) to establish obligations, guidelines or recommendations to improve and substantially tighten up the search systems in respect of information that is relevant (to genetic resources and traditional knowledge) so as to evaluate novelty and inventiveness.⁴

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." It is also important to emphasize the efforts and manifest interest of countries like Peru in making progress on implementation issues, as provided in paragraph 12 of the Declaration, which recognizes "*implementation-related ... concerns*", "*implementation problems faced by Members*", and hence the necessity that "*outstanding implementation issues shall be an integral part of the Work Programme*" established by Members.

³ The Group of Like-Minded Megadiverse Countries was officially set up in February 2002 as a policy coordination area for the main megadiverse countries (Cancún Declaration, Mexico). The Group has the following members: Brazil, Bolivia, China, Colombia, Costa Rica, Ecuador, India, Indonesia, Kenya, Madagascar, Malaysia, Mexico, Peru, Philippines, Venezuela.

⁴ Peru has also maintained a consistent position on the need to promote the development of an international regime on access to genetic resources and benefit-sharing (process under way in the CBD framework) and an international regime for protection of the traditional knowledge of indigenous and local communities. Thus, Decision VII/19 of the Seventh Conference of the Parties to the CBD, held in Kuala Lumpur, Malaysia (2004), established a negotiating mandate for this international regime. At its third meeting, held in Bangkok, Thailand, in February 2005, the Ad Hoc Open-Ended Working Group on Access and Benefit-Sharing initiated a technical analysis of the elements that could be included in the regime. This idea of an international regime emerged as a policy issue in 2002 in the context of proposals promoted by the Group of Like-Minded Megadiverse Countries (see footnote 3). At the same time, at Andean Community level and under the mandate established in Decision 391, Andean Community Decision 524, approved in 2004, set up a Working Group on the Rights of Indigenous Peoples tasked *inter alia* to promote development of a common regime (at regional level) for the protection of traditional knowledge.

Specifically, Peru contends that the following action is essential:

Revision of TRIPS and examination of its relationship with the CBD, addressing the issue of incorporating the requirement of legal provenance and disclosure of origin under the exclusions from patentability and under the conditions required for patent applications (Articles 27 and 29, respectively). It is hoped that the work leading up to the Sixth Ministerial Conference in Hong Kong in December 2005, and the text of the corresponding Declaration, will reflect this concern and establish a specific mandate for achieving this objective during and by the end of the Development Round.

II. INTRODUCTION

What common features are shared by resources such as hercampuri (*Gentianella alborosea* (Gilg) Fabris), camu camu (*Myrciaria dubia*), yacon (*Smallanthus sonchifolius*), caigua (*Cyclanthera pedata* L), sacha inchi (*Plukenetia volubilis* L), maca (*Lepidium meyenii*) and chanca piedra (*Phyllanthus niruri*)?

First of all, they are plants of Peruvian origin that serve useful purposes in human medicine and nutrition. Secondly, they are plants which for centuries have been conserved and used directly by small indigenous communities in the Andean and Amazon region, and whose characteristics, functions, properties, applications etc., are the subject of traditional knowledge. Thirdly, at the present day, they are plants with wider social uses, which in some cases have been industrialized in the wake of the opening up of markets (at national and international level) for products derived from them. Finally – and this is perhaps the most important element – they are plants which have given rise to inventions currently protected by patents granted principally in the United States, Europe and Japan. There are dozens of patents and large numbers of claims relating to these plants.⁵

Despite the difficulty and the fact that no exhaustive studies have as yet been carried out on the economic exploitation of genetic resources in Peru and the traditional knowledge associated therewith, a worldwide study conducted in 1999 concluded that the annual overall market value of genetic resources (used in biotechnology, the pharmaceutical industry, crop protection and bioremediation) is approximately US\$500-800 billion.⁶ Beyond the question of the actual figures – which may or may not be accurate – it is clear that genetic resources are extremely valuable. If we also take account of traditional knowledge that contributes to research and development processes - reducing research costs by 25 per cent - the (economic) value of these intangibles is also clearly seen to be very high.⁷

Given these circumstances, two questions arise that are fundamental to the discussions on the relationship between biodiversity, traditional knowledge and intellectual property:

⁵ See: document IP/C/W/441 (March 2005), Article 27.3(e), Relationship between the TRIPS Agreement and the CBD and Protection of Traditional Knowledge and Folklore, Communication from Peru dated 28 February 2005, Council for TRIPS, WTO. See also: document WIPO/GRTKF/IC/5/13, Patents Referring to *Lepidium meyenii* (maca): Responses of Peru. Document submitted by Peru at the fifth session of the WIPO Intergovernmental Committee. See also: Venero, Begonia. Addressing the Disclosure Requirement at the International Level – the Role of the TRIPS Agreement. ICTSD/CIEL/IDDRI/IUCN/QUNO Dialogue on Disclosure Requirements. WTO Public Symposium, Geneva, 21 April 2005.

⁶ Laird, Sarah, Ten Kate, Kerry. The Commercial Use of Biodiversity. Access to Genetic Resources and Benefit-Sharing. Earthscan Publications Ltd., London, 1999.

⁷ Balick, M.J. 1990. Ethnobotany and the identification of therapeutic agents from the rainforest. In: Chadwick, D.J (eds) Bioactive Compounds from Plants. Chichester, UK, Wiley & Sons, p.22.

- How and under what circumstances/conditions was access gained to these plants and the traditional knowledge associated therewith, thus giving rise to patentable inventions?
- Are the patents granted "good" patents in the sense that the inventions are actually new and involve an inventive step?

The first question is relevant to the extent that, since the entry into force of the CBD (1993), Peru has introduced specific standards regulating access to genetic resources (Andean Community Decision 391)⁸ and the protection of traditional knowledge (Law No. 27811).⁹ As from 1993, and more specifically since 1991 and 2002, access to genetic resources and the use of traditional knowledge have been governed by a set of principles and a series of standards, respectively, non-compliance with which implies that unauthorized or unlawful actions have been committed.

Concerning the second question, cases such as that of ayahuasca (US Plant Patent 5,751), quinoa (US Patent 5,304,718), the neem tree (US Patent 5,124,349 or patent No. 436 257 B1) granted by the European Patent Office or the turmeric plant (US Patent 5,401,504) have demonstrated that, in many instances, inventions relating to plants conserved and traditionally used by indigenous communities do not stand up to more rigorous assessments regarding novelty and inventiveness. This occurs because no account was taken, at the time of the assessment, of traditional uses that would have invalidated or impaired the claimed novelty and inventiveness.

Inasmuch as it is impossible for countries individually to be able to guarantee compliance with the conditions of access to their resources and protection of traditional knowledge, all countries have a responsibility to help ensure that the obligations and responsibilities established in the CBD (and incorporated in national legislation) are fulfilled.¹⁰ It is here that the intellectual property, and patent regime in particular can directly contribute to the fulfilment of the objectives of the CBD (in respect of access and benefit-sharing).

Accordingly, certain additional requirements could be established for the processing of patent applications so as to ensure that the patents granted are "good" ones, not based on unauthorized or even unlawful acts.¹¹ TRIPS establishes no specific limitations on the type of requirements applicable to operations under the system.¹² Specifically, the proposed requirements relate to disclosure of origin and legal provenance (of the resources or traditional knowledge that directly or indirectly could form part of the invention).

⁸ Andean Community Decision 391 on a Common Regime on Access to Genetic Resources (July 1996).

⁹ Law establishing the regime for protection of the collective knowledge of indigenous peoples relating to biological resources, 10 August 2002.

¹⁰ Although the United States has not *ratified* the CBD, the fact of having *signed* it places it under an obligation, pursuant to the principles set forth in the Vienna Convention on the Law of Treaties, not to interfere with efforts to achieve its effective and efficient implementation.

¹¹ For example, the consequences of not disclosing the origin of genetic material incorporated in an invention and non-compliance with legislation on access to genetic resources or protection of traditional knowledge, could invalidate the patent granted if the owner cannot prove that he is the actual inventor. Lack of candour in the provision of information could be sanctioned by non-application of the right granted (as occurs in the United States) (290 US 240, citing *Deweese v. Reinhard* 165 US 386).

¹² Additional requirements are not new to the patent system. In the case of biotechnological inventions, particularly as regards micro-organisms, the deposit of the micro-organism in question is deemed necessary to contribute to the full disclosure of the invention. The *Budapest Treaty on the International Recognition of the Deposit of Micro-organisms for the Purposes of Patent Procedures* (28 April 1977) establishes a deposit procedure and international authorities for the maintenance of inventions referring to micro-organisms. This requirement is universally considered necessary to promote the efficient operation of the system and is never criticized for hampering or undermining the way the system works.

At the same time, patent offices could be required to observe much stricter procedures when conducting searches for the assessment of novelty and inventiveness.^{13 14}

III. GENERAL CONTEXT AND DEFINITION OF THE PROBLEM

The reasons for the importance of the question of disclosure of origin and legal provenance are economic (genetic resources and traditional knowledge have economic significance and it is necessary to ensure the possibilities of their commercial exploitation and industrialization), legal (the need to grant "good" patent rights and the need for complementarities between legal regimes at the international level), cultural (the need to respect the beliefs and rights of indigenous peoples) and political (the need to safeguard countries' interests with regard to sovereign rights over their resources).

Compared with the situation some years ago, it has to be acknowledged that much progress has been made not only in the conceptual discussion on the disclosure of origin and legal provenance but also, and much more importantly, inasmuch as this topic is already the subject of policy negotiations in different fields and forums.

A group of countries particularly rich in biodiversity, which have historically been suppliers of genetic resources (and traditional knowledge), takes the view that the only way to enforce disclosure requirements is to ensure that they are recognized by the authorities of the countries in which most patents are granted.

Accordingly, these requirements should be incorporated in the legislation of the United States, Japan and the European countries and should form part of the administrative patent granting procedures of the US Patent and Trademark Office, the Japan Patent Office and the European Patent Office, respectively. A first step would be the inclusion of these requirements in the text of the TRIPS Agreement.

It has to be acknowledged that even in the best of cases, i.e. when disclosure of origin and legal provenance is recognized in the United States, Europe and Japan, not all the problems associated with the unauthorized or unlawful use of resources and associated traditional knowledge will be resolved.¹⁵

However, such recognition has a number of immediate positive implications which deserve mention:

¹³ This idea has been raised in some judicial decisions in the United States, on the basis of *Corona Cord Tire Co. v. Dovan Chem. Corp.* (US Supreme Court, 1928). In that case, a prior invention that was not publicly known served to invalidate the novelty of a second invention.

¹⁴ See: Center for International Environmental Law (CIEL). *Comments on Improving Identification of Prior Art. Recommendations on Traditional Knowledge Relating to Biological Diversity Submitted to the United States Patent and Trademark Office*, 2 August 1999. See also: Ruiz, Manuel. *The International Debate on Traditional Knowledge as Prior Art in the Patent System: Issues and Options for Developing Countries*. Trade Related Agenda, Development and Equity. Occasional Papers 9, South Centre, October, 2002.

¹⁵ Situations may arise where: it is impossible to determine the origin of a resource (or of components of an invention); the invention relates to derived or synthesized products that differ substantially from the original resources; the information on traditional knowledge may not have been available at the time of the assessments; etc. Nevertheless, the proposed changes to the system would in fact have practical effects in some circumstances (without entailing an excessively high cost/benefit ratio) and would in particular reflect an element of political will and good faith tending to generate consensus and the search for appropriate solutions.

- Re-establishment of trust-based relations between ("Southern") countries traditionally considered to be suppliers of resources and ("Northern") countries traditionally considered to be users;
- improved conditions for the establishment of regimes of access to genetic resources and protection of traditional knowledge that are less authoritarian and restrictive;
- elaboration of common but differentiated commitments and obligations in accordance with a basic CBD principle;
- contribution to ensuring that "good" rights (legal certainty) are granted under the intellectual property system and the patent system in particular; and
- establishment of positive synergies and complementarity between the CBD and the intellectual property system, TRIPS in particular.

IV. BACKGROUND ON PERU'S POSITION IN RECENT YEARS

The earliest instance of Peruvian representatives putting forward an explicit proposal on the need to link the patent system with the regime of access to genetic resources (and with protection of traditional knowledge) was at a regional workshop on access to genetic resources held in August 1994 at Villa de Leyva, Colombia, in the context of the elaboration of Andean Community Decision 391 on access to genetic resources.¹⁶ Subsequently, when negotiations on the Andean access regime were initiated in 1995, at the Third Meeting of Governmental Experts, greater attention began to be paid to this type of proposal. During the Second Conference of the Parties to the CBD (Jakarta, 1995), Peru also raised this idea in the course of the negotiating sessions. Later on, at the various conferences of the parties held to date (and at the meetings of the Subsidiary Body on Scientific, Technical and Technological Advice), contributions were also made in this regard.

Initially viewed with some suspicion, this idea has gradually evolved, has received various inputs and has been considerably refined, so much so that it has become a negotiating position uniting the interests of many countries, especially developing countries with substantial biodiversity in their territories.

Peru, together with other countries, has since 1994 been fostering and promoting the idea of disclosure of origin and legal provenance in different forums. In this connection, as was already stated, it has maintained a steadfast position on the subject, both within the CBD and in WIPO, the WTO and various other forums (including regional processes).

Peru's official position is that it advocates amendment of the TRIPS Agreement to include the requirement that an applicant for a patent on biological materials or traditional knowledge disclose the source and country of origin of the resource used in the invention, as well as evidence of prior informed consent and fair and equitable benefit-sharing. These three elements are necessary for the prevention of biopiracy and bad patents, and this position has been upheld in numerous statements and contributions (presented individually or in conjunction with countries with similar interests), in different forums, especially the WTO. It is reflected in numerous documents:

¹⁶ Subsequently, at the Second Conference of the Parties to the CBD (Jakarta, Indonesia, 1995), in the context of the Global Biodiversity Forum, there was a discussion on the document by Tobin, Brendan. *Certificates of Origin. A Role for IPR Regimes in Securing Prior Informed Consent* (Peruvian Environmental Law Society, Lima, 1995), which contained the first ever detailed analysis of the possibility and viability of linking the regime on access (and protection of traditional knowledge) with the intellectual property system.

- Document WT/GC/W/362 (October 1999) – Proposal on Protection of the Intellectual Property Rights Relating to the Traditional Knowledge of Local and Indigenous Communities. Communication from Bolivia, Colombia, Ecuador, Nicaragua and Peru, 4 October 1999. General Council, WTO.
- Document WT/CTE/W/176 (October 2000)/IP/C/W/246 (March 2001) – Peru's Experience of the Protection of Traditional Knowledge and Access to Genetic Resources. Communication from Peru to the Committee on Trade and Environment and to the TRIPS Council, respectively, WTO.
- Document IP/C/W/403 (June 2003) – The Relationship between the TRIPS Agreement and the Convention on Biological Diversity and the Protection of Traditional Knowledge. Submission by Bolivia, Brazil, Cuba, Dominican Republic, Ecuador, India, Peru, Thailand and Venezuela. TRIPS Council, WTO.
- Document IP/C/W/420 (March 2000) – The Relationship between the TRIPS Agreement and the Convention on Biological Diversity (CBD). Checklist of issues. Submission from Brazil, Cuba, Ecuador, India, Peru, Thailand and Venezuela, 26 February 2004. TRIPS Council, WTO.
- Document IP/C/W/429 (September 2004) – Elements of the Obligation to Disclose the Source and Country of Origin of the Biological Resources and/or Traditional Knowledge Used in an Invention. Submission from Brazil, India, Pakistan, Peru, Thailand and Venezuela, 20 September 2004. TRIPS Council, WTO.
- Document IP/C/W/438 (December 2004) – The Relationship Between the TRIPS Agreement and the Convention on Biological Diversity (CBD) and the Protection of Traditional Knowledge – Elements of the Obligation to Disclose Evidence of Prior Informed Consent under the Relevant National Regime. Submission from Bolivia, Brazil, Cuba, Ecuador, India, Pakistan, Peru, Thailand and Venezuela, 30 November 2004. TRIPS Council, WTO.
- Document IP/C/W/441 (March 2005) – Article 27.3(b), Relationship between the TRIPS Agreement and the CBD and Protection of Traditional Knowledge and Folklore. Communication from Peru, 28 February 2005. TRIPS Council, WTO.
- Declaration of the Andean Countries on Promoting Disclosure of Origin in the WTO Negotiations Relating to Intellectual Property and Protection of Biodiversity. 90th Ordinary Session of the Commission of the Andean Community, Lima, 28 March 2005.
- Statements by the Permanent Representative of Peru to the WTO Trade Negotiations Committee on 21 March and 19 May 2005, and to the General Council on 26 May 2005.

In other regional and bilateral negotiating forums, Peru has expressed the same interest and presented relevant proposals. For example, in the context of the FTAA (Free Trade Area of the Americas) negotiations, Peru and the other Andean countries submitted proposals for specific provisions on access to genetic resources and traditional knowledge to be included in the chapter on intellectual property. Similarly, in the free trade agreement negotiations between Colombia, Ecuador

and Peru, on the one hand, and the United States, on the other, proposals on this subject were also put forward.¹⁷

V. DEVELOPMENTS IN RESPECT OF PUBLIC POLICY AND LEGISLATION (IN PERU AND THE ANDEAN REGION)

Regulation on protection of plant varieties. The first legal precedent anywhere in the world that establishes a direct and explicit link between intellectual property and access to genetic resources and protection of traditional knowledge can be found in Peru's regulation on protection of plant varieties.¹⁸ This regime determines the rules and the institutional framework applicable to the protection of the rights of plant breeders.

Article 15 of the Regulation provides that the application "*for the granting of a breeder's certificate shall be submitted to the Office of Inventions and New Technologies [of INDECOPI] and shall contain or have attached, as appropriate ...*

- (e) the geographical origin of the raw plant material of the new variety to be protected, including, where appropriate, the document certifying the legal provenance of the genetic resources, issued by the competent authority, with respect to access to genetic resources,
- (f) the origin and genetic content of the variety, including any known details with regard to the source of the genetic resources used in the variety or the breeding thereof, as well as any information on knowledge relating to the variety [including traditional knowledge], where appropriate".

The penalty for not submitting the required information, under Article 16 of the Supreme Decree, is that the application shall be declared to have lapsed.

Andean Community Decision 391. Decision 391 is the first regional enactment regulating the terms and conditions of access to genetic resources in the countries of the region. As a result of formal proposals made by Peru and Colombia at the negotiating meetings on the Andean regime on access to genetic resources, Andean Community Decision 391¹⁹ provided for the adoption of legal requirements at regional level (valid only among the five countries of the Andean Community), which directly link the access regime to intellectual property and patents in particular.

The Second Supplementary Provision of Decision 391 provides that:

"The Member Countries shall not acknowledge rights, including intellectual property rights, over genetic resources, by-products or synthesized products and associated intangible components [including traditional knowledge], that were obtained or developed through an access activity that does not comply with the provisions of this Decision.

Furthermore, the Member Country affected may request nullification and bring such actions as are appropriate in countries that have conferred rights or granted protective title documents".

¹⁷ Negotiations on the US-Colombia, Ecuador, Peru Free Trade Agreement were started in May 2004.

¹⁸ Supreme Decree No. 008-96-ITINCI, Regulation on protection of the rights of breeders of new plant varieties, 6 May 1996, which regulates the implementation of Decision 345 on Common Provisions on the Protection of the Rights of Breeders of New Plant Varieties.

¹⁹ Andean Community Decision 391 on a Common Regime on Access to Genetic Resources, approved on 2 July 1996.

In much more specific terms, the Third Supplementary Provision provides that:

"The competent national offices on intellectual property shall require the applicant to give the registration number of the access contract and supply a copy thereof as a prerequisite for granting the respective right, when they are certain or there are reasonable indications that the products or processes whose protection is being requested have been obtained or developed from genetic resources or their by-products originating in any one of the Member Countries.

The competent national authority and the competent national offices on intellectual property shall establish systems for exchanging information about the authorized access contracts and intellectual property rights granted".

This regulation marks a milestone in comparative legislation by establishing as a condition for granting an intellectual property right (and more particularly a patent for invention) that there be compliance with requirements under a different legal regime, in this case one relating to access to genetic resources.

Andean Community Decision 486. Decision 486 establishes the legal industrial property framework (patents, designs, utility models, marks, etc.) applicable in the countries of the Andean region. Consolidating the idea of disclosure of origin and legal provenance, Andean Community Decision 486²⁰ incorporated rules on this subject for the first time in a standard-setting intellectual property enactment of regional scope *per se*.

Article 26(h) and (i) of the Decision provides that applications for patents shall contain:

"(h) if applicable, a copy of the access contract, where the products or processes for which a patent application is being filed were obtained or developed from genetic resources or by-products originating in any one of the Member Countries;

(i) if applicable, a copy of the document certifying the licence or authorization to use the traditional knowledge of indigenous, African American or local communities in the Member Countries, where the products or processes whose protection is being requested were obtained or developed from such knowledge originating in any one of the Member Countries, in accordance with the provisions of Decision 391 and the amendments and regulations thereto currently in force;"

Article 75(g) and (h) of Decision 486 goes a little further by providing that a patent shall be declared absolutely void if the applicant has failed to submit a copy of the access contract or the document certifying the licence or authorization for use of traditional knowledge.

The Law on Collective Knowledge. Law No 27811 is the first law enacted for the protection of traditional knowledge associated with biological diversity in particular. Through a system of registers, licences and compensatory mechanisms, it is hoped to achieved a degree of legal protection for the traditional knowledge of Peru's indigenous peoples.

In the matter of disclosure of origin and legal provenance, the Second Supplementary Provision of Law 27811 provides that:²¹

²⁰ Andean Community Decision 486 on a Common Industrial Property Regime, 14 September 2000.

²¹ Law Establishing the Regime for Protection of the Collective Knowledge of Indigenous Peoples Relating to Biological Resources, 10 August 2002.

"Where a patent application relates to products or processes obtained from collective knowledge, the applicant shall be required to submit a copy of the licence contract, as a prerequisite for the granting of the relevant right, unless the collective knowledge concerned is in the public domain. Failure to comply with this obligation shall be grounds for refusing to grant the patent or, where appropriate, declaring it void."

This provision supplements at national level the provisions of Decision 486, specifically with regard to the disclosure of the origin and legal provenance of traditional knowledge that could form part of an invention.

Law No. 28216 and the National Commission on Prevention of Biopiracy. Lastly, Law No. 28216, under which a National Commission for the Protection of Access to Peruvian Biological Diversity and Collective Knowledge (commonly known as the Commission for Prevention of Acts of Biopiracy)²² was formally established, provides for a series of measures to deal with the phenomenon of biopiracy (see final paragraph for the definition of "biopiracy").

The Commission's functions, as defined in Article 4, include the following:

"(c) To identify and follow up patent applications made or patents granted abroad that relate to Peruvian biological resources or collective knowledge of the indigenous peoples of Peru;

(d) to make technical evaluations of the patent applications or patent grants referred to in the preceding paragraph;

(e) to issue reports on the cases studied, and to transmit recommendations to the competent State authorities;

(f) to lodge objections or institute actions for annulment concerning patent applications made or patents granted abroad that relate to Peruvian biological or genetic material or the collective knowledge of the indigenous and native peoples of Peru".

The third and final supplementary provision of the Law defines "biopiracy" as *"access to and unauthorized use without compensation of biological resources or traditional knowledge of the indigenous people by third parties, without the necessary authorization and in contravention of the principles established in the Convention on Biological Diversity and the existing rules on the subject. This appropriation may come to light through physical inspection, through ownership rights in products incorporating such illegally obtained elements or, in some cases, through the invocation of such rights"*.

Peru is making strenuous efforts to achieve the effective and efficient implementation of this regulatory framework. INDECOPI, with the support of a number of institutions (including the Peruvian Institute for Natural Products, the Peruvian Environmental Law Society, the Confederation of Amazonian Communities of Peru, the Ministry of Foreign Trade and Tourism, among others), is engaged in a major campaign to raise the indigenous communities' awareness of these issues and of their outstanding importance. At the same time, INDECOPI, as coordinator of the National Commission on Prevention of Biopiracy, is working among other things on implementation of the National Public Register of Collective Knowledge, establishment of an institutional portal on collective knowledge, and a regular search facility for patents relating to genetic resources and traditional knowledge of Peruvian origin.

²² Law on Protection of Access to Peruvian Biological Diversity and to the Collective Knowledge of the Indigenous Peoples, 1 May 2004.

VI. POLICY AND REGULATORY ADVANCES IN OTHER COUNTRIES²³

Following the example of Peru and the Andean region, various countries have adopted policies and regulations that incorporate requirements relating to disclosure of origin and legal provenance.

Costa Rica. In 1998, Costa Rica approved the Law on Biodiversity (Law No. 7788) which included provisions on disclosure of origin and legal provenance.

Article 80 of the Law provides that both *"The National Seeds Office and the Intellectual and Industrial Property Registries must compulsorily consult the Technical Office of the Commission [National Biodiversity Management Commission] before granting intellectual or industrial property protection to innovations that involve elements of biodiversity. They shall in all cases submit the certificate of origin issued by the Technical Office of the Commission and the prior consent. Reasoned opposition by the Technical Office shall prevent registration of the patent or protection of the innovation"*.

Central America . Also in 1998, a draft Central American Protocol on Access to Genetic and Biochemical Resources and Associated Traditional Knowledge was approved. Article 26 of the Draft provides that *"upon registration of products and processes that may involve the use of resources and knowledge, the intellectual property registries and competent authorities, as appropriate, shall require submission of the certificate of origin demonstrating lawfulness of access. Any failure to comply with this provision or any violation of the laws on access or of the conditions of contracts for access shall cause approval or registration to be withheld from the applicant"*.

Venezuela. The Law on Biological Diversity is an omnibus enactment which deals mainly with the conservation of diversity and its components. It also contains specific chapters on access to genetic resources and intellectual property rules.²⁴

Article 82 of the Law provides that **"intellectual property rights over collected samples or parts thereof shall not be recognized where they have been acquired illegally or where they involve the collective knowledge of local indigenous peoples and communities"**.

Brazil. In 2001, Brazil adopted Provisional Measure 2186-16.²⁵ This measure governs, among other things, access to the genetic heritage of Brazil and matters relating to technology transfer and the protection of traditional knowledge.

Article 31 of the Provisional Measure provides that **"the granting by the competent bodies of industrial property rights over the process or products obtained from the sample of the component of the genetic heritage shall be conditional on compliance with this Provisional Measure and, where appropriate, the applicant shall provide information on the origin of the genetic material and associated traditional knowledge"**.

India. Section 6(1) of India's Biodiversity Act, approved in 2002, provides that **"no person shall apply for any intellectual property right, by whatever name called, in or outside India, for any invention based on any research or information on a biological resource obtained from India without**

²³ Highlights in the texts are designed to identify the precise location of references to disclosure of origin and legal provenance.

²⁴ Law No. 4,780, Law on Biological Diversity (2000).

²⁵ Provisional Measure 2186-16 regulating sections II.1 and II.4 of Article 225 of the Constitution, Articles 1, 8(j), 10(c), 15 and 16 of the CBD, provisions on access to the genetic heritage, protection and access to associated traditional knowledge, benefit-sharing and access to technology for conservation and transfer, among other things (August 2001).

obtaining the previous approval of the National Biodiversity Authority before making such application. Provided that if a person applies for a patent, permission of the National Biodiversity Authority may be obtained after the acceptance of the patent but before confirmation of the patent by the patent authority concerned".

Some developed countries have also adopted changes to their regulatory frameworks and public policies so as to make explicit provision for the requirement of disclosure of origin.

Switzerland. In May 2003, the Government of Switzerland submitted to the WIPO Working Group on Reform of the Patent Cooperation Treaty a proposal on disclosure of the origin of genetic resources and traditional knowledge in patent applications. Specifically, Switzerland proposes amending the PCT regulations to include a new rule 51 bis 1(g), which would enable PCT member States to require disclosure of the origin of genetic resources and traditional knowledge used for inventions that could include those elements.

Norway. Norway recently approved an amendment to its patent legislation, providing for the inclusion of a disclosure requirement in respect of the origin of genetic resources. Failure to provide the required information would entail refusal to process the application or annulment of the patent granted, as applicable.

The Norwegian Patents Act and the most recent amendments thereto (in force since May 2004) provide as follows in section 8(b):

"If an invention concerns or uses biological material, the patent application shall include information on the country from which the inventor collected or received the material (the providing country). If it follows from the national law in the providing country that access to biological material shall be subject to prior consent, the application shall state whether such consent has been obtained.

If the providing country is not the same as the country of origin of the biological material, the application shall also state the country of origin. The country of origin means the country from which the material was collected from its natural environment. If the national law in the country of origin requires that access to biological material shall be subject to prior consent, the application shall state whether such consent has been obtained. If the information set out in this subsection is not known, the applicant shall so indicate.

The duty to disclose information under the first and second paragraphs applies even where the inventor has altered the structure of the material received. The duty to disclose information does not apply to biological material derived from the human body. Breach of the duty to disclose information is subject to penalty in accordance with the General Civil Penal Code §166. The duty to disclose information is without prejudice to the processing of patent applications or the validity of rights arising from granted patents".

European Directive. There are other examples of approved regulations, where the negotiations and preliminary texts included consideration of the requirement of disclosure of origin. This is the case in particular for the European Directive on the legal protection of biotechnological inventions, Directive No. 98/44/EC. Preambular paragraph 27 of the Directive contains a reference to disclosure in the following terms:

"Whereas if an invention is based on biological material of plant or animal origin or if it uses such material, the patent application should, where appropriate, include information on the geographical origin of such material, if known; whereas this is without prejudice to the processing of patent applications or the validity of rights arising from granted patents".

These cases serve to demonstrate that advances are already being made in respect of public policy and specific regulations which, with different degrees of detail and binding force, recognize requirements concerning disclosure of origin and legal provenance of genetic resources and traditional knowledge.

VII. PROPOSALS FOR THE INTERNATIONAL AND REGIONAL NEGOTIATING AGENDA

The CBD process and the WIPO Intergovernmental Committee have, of course, shown flexibility in the discussion of issues relating to disclosure.²⁶ In short, in conceptual terms, considerable progress has been made since 1995 in the analysis and discussion of the legality of these requirements, their economic implications for the intellectual property system (and the patent system in particular), their practical effects and their political repercussions.

In terms of effectiveness, however, the TRIPS review process under way in the WTO (pursuant to instructions originally set out in paragraph 19 of the Doha Declaration - see footnote 2) and the binding nature of the WTO mandates make this the ideal forum for incorporating requirements concerning disclosure of origin and legal provenance in the text of the TRIPS Agreement. The mandate contained in paragraph 12 of the Doha Declaration in respect of *implementation* also makes this forum particularly relevant.

Specifically, Peru proposes an amendment to Article 27 of the TRIPS Agreement in the form of a further exception to patentability, with the following wording [Members may also exclude from patentability]:

"(c) products or processes which directly or indirectly include genetic resources or traditional knowledge obtained in the absence of compliance with international and national legislation on the subject, including failure to obtain the prior informed consent of the country of origin or the community concerned and failure to reach agreement on conditions for the fair and equitable sharing of benefits arising from their use.

Nothing in TRIPS shall prevent Members from adopting enforcement measures in their domestic legislation, in accordance with the principles and obligations enshrined in the Convention on Biological Diversity".

This exception establishes that patents should not be granted in cases of infringement or breach of binding rules under other legal regimes directly related to possible inventions, especially in the biotechnological field. The regimes concerned are those governing access to genetic resources and the protection of traditional knowledge.

Peru also proposes an amendment to Article 29(1), consisting in the addition of a paragraph which expressly provides as follows:

"Where appropriate, Members shall require the disclosure of origin and legal provenance in the patent applications to be submitted".

It will left to countries to define in their domestic legislation the penalties applicable in cases of failure to comply with this rule. The options in this connection include not processing an

²⁶ The most recent and comprehensive study prepared on this topic by the WIPO Secretariat is document WIPO/IP/GR/05/3, Examination of Issues Relating to the Interrelation of Access to Genetic Resources and Disclosure Requirements in Intellectual Property Rights Applications (May 2005), a document which will be submitted at the Ad Hoc Meeting on genetic resources and disclosure requirements, Geneva, 3 June 2003.

application, pending compliance with the proposed requirements, declaring the application to have lapsed if these requirements are not met during the review procedure, declaring nullity (incurable or relative, i.e. remediable), if the patent is granted and non-compliance is subsequently ascertained, etc.

The Sixth WTO Ministerial Conference in Hong Kong, to be held in December 2005, should include in its agenda and subsequent Declaration an explicit reference to the question of the relationship between intellectual property, biodiversity and traditional knowledge and the need to establish positive synergies between TRIPS and the CBD. These synergies include recognition, in the context of the disclosure of origin and legal provenance, of suitable means for establishing a direct connection between the intellectual property regime and the regime for access to genetic resources (and protection of traditional knowledge) and for guaranteeing, in the final analysis, that the objectives of both regimes are satisfactorily fulfilled.
