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COMBATING BIOPIRACY – THE PERUVIAN EXPERIENCE

Document submitted by Peru

1. In a communication dated July 6, 2007, the Permanent Mission of Peru before the International Organizations in Geneva submitted a document entitled “Combating Biopiracy – the Peruvian Experience”.
2. The text of this document appears in the form received in the Annex to this document.
3. *The Intergovernmental Committee is invited to take note of the contents of the Annex when it examines item 9 of the Agenda on genetic resources.*

[Annex follows]

ANNEX

COMBATING BIOPIRACY – THE PERUVIAN EXPERIENCE

PERU: A MEGADIVERSE COUNTRY

Peru is rich in genetic diversity due to the fact that it is one of the world's centers of origin of agriculture and livestock farming. As a result, it is one of the world's major centers for plant and animal genetic resources (CONAM, 1999).

There are thought to be around 20,000 higher plant species in Peru (10% of the world's total), of which 5,509 are endemic (approximately 27%) (Leon, B., 2006). It ranks fifth in the world for number of species, first for number of plant species with properties known and used by the population (4,400 species) and first for native domesticated species (128). It has 182 domestic native plant species, with hundreds or even thousands of varieties, of which 174 are of Andean, Amazonian and coastal origin and 7 are of American origin, having been introduced centuries ago. In addition, it has the wild forms of these plants (Brack, A., 2005).

The number of species with a current or potential industrial application is high at 2,642. Of those species, 682 are sources of food, 1,044 are medicinal, 444 provide timber resources, 86 are forage plants, 55 are used to obtain fertilizers, 60 are used in oils and fats, 46 in aromas and perfumes, 75 in cosmetic products, 22 in tanning products, and 128 in dyes and colorants. The country ranks very highly in terms of fruits (623 species), medicinal plants (1,408 species) and ornamental plants (1,600 species) (Brack, A., 2005).

Peru is a multiethnic and multicultural country, as shown by the fact that it has 14 linguistic families and 72 ethnic groups (*Mapa Etnolingüístico Oficial del Perú*, Ministry of Agriculture/Indigenous Institute of Peru, 1994). It is home to approximately 28 million inhabitants and, according to the latest statistical data on the indigenous Peruvian population, there are 8,793,295 natives, of whom 97.8 per cent are Andean (of whom 90.9 per cent are Quechuan and 6.9 per cent Aymara) and 2.1 per cent are Amazonian. According to these figures, the indigenous population represents one-third of the country's inhabitants. This indigenous population lives mainly in the country's rural area, grouped together in 5,812 rural communities (Andean) and 1,315 native communities (Amazonian).

These indigenous peoples are the heirs to the former Peruvians who, more than 10,000 years ago, domesticated and diversified plant and animal species for different uses, and are at present the depositary of a rich heritage of traditional knowledge concerning the use of those species.

The rich biological and cultural diversity of Peru has prompted its interest in protecting it and in developing actions such as those described in this document.

BACKGROUND AND CONTENTS OF THE REPORT

In mid-2002, the National Institute for the Defense of Competition and Intellectual Property Protection (INDECOPI) convened a meeting of Peruvian governmental institutions and non-governmental organizations to analyze the patents granted and pending patent applications referring to *Lepidium meyenii* (maca) and their consequences, and also to assess alternatives to tackle them. The Working Group drew up a report entitled “Patents referring to *Lepidium Meyenii* (Maca): Responses of Peru” which was submitted by the Delegation of Peru at the Fifth Session of the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore, which took place from July 7 to 15, 2003.

Later, the National Commission for the Protection of Access to Peruvian Biological Diversity and to the Collective Knowledge of the Indigenous Peoples (hereinafter “the National Anti-Biopiracy Commission”) was created, which, since its creation in May 2004, has been carrying out actions to identify and follow up patent applications filed or patents granted abroad that relate to Peruvian biological resources or to collective knowledge of the indigenous peoples of Peru.

The National Anti-Biopiracy Commission has drawn up various documents which have been submitted by the Delegation of Peru in various international fora(including WIPO and the WTO):

- At the Eighth Session of the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore, held from June 6 to 10, 2005, document WIPO/GRTKF/IC/8/12¹ was submitted, entitled “Patent System and the Fight against Biopiracy – The Peruvian Experience”, which sets out the results of the search for potential cases of biopiracy of six resources of Peruvian origin (hercampuri, camu camu, yacón, caigua, sacha inchi and chancapiedra) that was made using the databases accessible through the websites of the United States Patent and Trademark Office, the European Patent Office and the Japan Patent Office.
- At the Ninth Session of the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore, held from April 24 to 28, 2006, document WIPO/GRTKF/IC/9/10² was submitted, entitled “Analysis of Potential Cases of Biopiracy: The Case of Camu Camu (*Myrciaria Dubia*)”, describing the progress made in identifying and analyzing patent applications and patents concerning inventions obtained or developed through the use of camu camu (*Myrciaria dubia*). It also contained some comments on the limitations and problems that countries such as Peru faced or may face in identifying, monitoring and studying patent applications or patents that involve improperly granted rights (because they do not meet patentability criteria) or weaken regimes for access to genetic resources and/or protection of traditional knowledge.

¹ A similar document was submitted to the World Trade Organization (WTO), with reference IP/C/W/441, dated March 8, 2005, and its revised version IP/C/W/441/Rev.1, dated May 19, 2005.

² A similar document was submitted to the WTO, with reference IP/C/W/458, dated November 7, 2005.

Peru has been one of the main driving forces behind the idea of modifying and adjusting the international patent system to include requirements on disclosure of the origin and legal

source of genetic resources and traditional knowledge. In the case of Peru, these requirements were originally incorporated in Supreme Decree 008-06-ITINCI (1996), establishing regulations for the Andean protection regime for the rights of breeders of new plant varieties. Almost successively, Decision 391 of the Andean Community of Nations, establishing a Common Regime on Access to Genetic Resources (July 1996), also incorporated these requirements in a much more explicit manner, linking the intellectual property regimes to the regime for access to genetic resources and protection of traditional knowledge. A few years later, Decision 486 of the Andean Community of Nations, establishing a Common Industrial Property Regime (September 2000), included, among the documents that must accompany patent applications, where applicable: (a) a copy of the access contract, where the products or processes which are the subject of the patent application were obtained or developed using genetic resources or byproducts originating in any of the Member Countries, and (b) a copy of the document that certifies the license 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 using the knowledge originating in any of the Member Countries, pursuant to the provisions of Decision 391 and its effective amendments and regulations. Finally, in August 2002, Law No. 27811 was adopted, introducing a Protection Regime for the Collective Knowledge of Indigenous Peoples Derived from Biological Resources.

At the international level, since 1994, Peru has been submitting proposals on the need to link the patent system to the regime for access to genetic resources and to the protection of traditional knowledge in the CBD, WIPO and WTO, as well as in other fora (including regional processes). In this regard, in the context of the Doha Round and with document IP/C/W/447, dated June 8, 2005, Peru proposed that the TRIPS Agreement be amended to include the requirement that an applicant for a patent relating to biological material 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 of fair and equitable benefit-sharing.

On May 29, 2006, Peru, Brazil, India, Pakistan, Thailand and Tanzania also presented document WT/GC/W/564/TN/C/W/41 to the Trade Negotiations Committee, which rightly proposes amendments to the TRIPS Agreement in line with the proposals outlined. These proposals were subsequently supported by the large majority of developing countries.

Later, on November 2, 2006, document IP/C/W/484 was submitted, entitled “Response to Comments Contained in Document IP/C/W/469 Relating to the Peruvian Communication IP/C/W/458”, in which it is concluded that Peru’s position is clear in considering that, even though there are useful tools to improve the patent system – and to verify compliance with the obligations in place relating to patentability requirements, in particular relating to novelty and inventive step – the inclusion of the requirement to disclose the source and/or origin of biological resources proposed in document IP/C/W/473 is an imperative if the aim is for the patent system to complement fully the obligations arising from the CDB, which Peru and all Member States are obliged to fulfill.

This report describes the process carried out by the Commission to identify cases of biopiracy, as well as the administrative actions initiated against pending patent applications referring to inventions obtained or developed through the use of a resource of Peruvian origin (in some cases using traditional knowledge of Peru’s indigenous peoples), where it has been identified that the patentability requirements have not been fulfilled.

It also sets out the limitations and problems faced in identifying, monitoring and analyzing patent applications or patents that involve improperly granted rights because they do not meet patentability requirements or because they weaken regimes for access to genetic resources and/or protection of traditional knowledge.

PROCEDURE FOLLOWED BY THE COMMISSION TO IDENTIFY CASES OF BIOPIRACY

Due to the Commission's limited resources and also as a result of Peru's enormous biological and cultural wealth, the country's National Anti-Biopiracy Commission was obliged to focus its efforts on particular resources, choosing to give priority to 35 resources (33 plant and 2 animal) to identify possible cases of biopiracy in patent applications and patents granted.

The criteria for selecting those resources included the following:

- volume of internal and external commercialization;
- endemism;
- resources or traditional knowledge which are the subject of investigation;
- rights granted (known patents).

The Commission has carried out, and carries out periodically, searches on four databases, using as search criteria the most well-known common names, the scientific name, the synonyms and sometimes the genus of the species to which the 35 resources belong. The following databases are used:

- database of the United States Patent and Trademark Office (www.uspto.gov)
- database of the Japan Patent Office (<http://www.jpo.go.jp>)
- database of the European Patent Office (<http://ep.espacenet.com>)
- database of the World Intellectual Property Organization (<http://www.wipo.int>)

Such searches make it possible to identify the patent applications or patents which make any reference to the resource. A preliminary analysis of the references found is then carried out, to identify in which there is really a direct reference to the resource that is the subject of the search. Once this has been carried out, the references are evaluated to determine the level of use of the resource or traditional knowledge, whether there is any reference to the origin of the resource or traditional knowledge, as well as what the claims are. Once this information has been gathered, experts in the resource in question are contacted, as well as businesses working with that resource, so that they may provide the Commission with information to enable it to identify the most relevant prior art.

Once the most relevant prior art has been identified, the application is analyzed to determine whether the patentability requirements, in particular novelty and inventive step, have been met

All this information is submitted to the Commission for its consideration so that it may determine whether the case analyzed should be regarded as a case of biopiracy, and if so, what action should be taken. The help of an expert in the resource may be sought to determine whether there is a case of biopiracy.

ACTION CARRIED OUT BY THE COMMISSION IN IDENTIFIED CASES OF BIOPIRACY

The cases of biopiracy identified by the Commission to date are detailed below, as well as the action taken by the Commission in those cases.

1 Functional Food Product Containing Maca (Publication No. 2004-000171)

TYPE: Patent application

APPLICANT: Towa Corp (Japan)

COUNTRY: Japan

DATE OF PUBLICATION: January 1, 2004

MAIN CLAIM:

Functional food product, characterized by its maca content and its effect of increasing growth hormone levels in blood.

PRIOR ART FOUND BY THE COMMISSION:

A publication by a Peruvian scientist (*Revista Peruana de Biología*, 1990) mentioning experimental testing of the effect of extracts of maca on growth and development in rats. The author in question suggests that the maca extract is effective on the production of hormones in the pituitary gland. It is known that one of the hormones produced by this gland is the growth hormone.

ACTION: On March 8, 2006, an e-mail and fax were sent to the Japan Patent Office (JPO), requesting that it consider the texts mentioned as support for a declaration that the patent application did not meet the requirements of novelty and inventive step. The technical documentation supporting the claim was also sent to the Japan Patent Office.

CURRENT STATUS: Application rejected. However, the Japan Patent Office did not use the information that was sent to it in good time.

2. Extract of *Lepidium meyenii* roots for pharmaceutical applications (US 6297995)

TYPE: Patent

APPLICANT: Pure World Botanicals, Inc. (USA)

COUNTRY: United States

DATE OF PUBLICATION: July 31, 2001

DERIVED PATENTS:

Treatment of sexual dysfunction with an extract of *Lepidium meyenii* roots (US 6,428,824)

Compositions and methods for their preparation from *Lepidium* (US 6,552,206)

MAIN CLAIM:

An isolated composition obtained by extracting *Lepidium meyenii* roots, said composition being substantially free of cellulose and comprising:

- a) between about 5% and about 9% of benzyl isothiocyanate,
- b) between about 1% and about 3% of *Lepidium* sterol component,
- c) between about 20% and about 30% of *Lepidium* fatty acid component, and
- d) about 10% or more of macamide component.

ACTION: Action is being carried out to request that the patent be challenged.

CURRENT STATUS: Patent granted

3. Preserves of fruit of *Myrciaria dubia*

(Publication No. 09 – 215475)

TYPE Patent application

APPLICANT: T Hasegawa Co. Ltd. (Japan)

COUNTRY: Japan

DATE OF PUBLICATION: August 18, 1997

MAIN CLAIM:

Preserves containing whole fruit of camu camu, minerals and peptic substances.

PRIOR ART FOUND BY THE COMMISSION:

The following publications were found:

- Alvarado (1969)³[3]^[1] and Calzada (1980), mentioning the use of the fruit of camu camu in the preparation of juices and strong alcohols using the pulp, as well as in the preparation of ice creams and jams.
- Thesis by Sanjurjo (1990), describing the process of producing juice, jam and jelly from the pulp of camu camu. It is also indicates that jam contains the pulp of camu camu, pectin and sugar, adding bits of other fruits such as pineapple to improve flavor.
- Villachica (1996), citing the thesis by González (1987) entitled ‘ Estudio técnico sobre la elaboración de conservas de camu camu (*Myrciaria dubia*)’ . [Technical study on the preparation of preserves using camu camu (*Myrciaria dubia*).]

ACTION: A communication was sent to the Japan Patent Office requesting that the patent application be rejected due to lack of novelty. The documentation supporting the request was enclosed with the communication.

CURRENT STATUS: Application abandoned.

4. Utilisation d’huile et de protéines extraites de graines de Plukenetia volubilis linneo dans des préparations cosmétiques, dermatologiques et nutraceutiques. [Use of oil and proteins extracted from the seeds of Plukenetia volubilis linneo in cosmetic, dermatological and nutraceutical preparations.]

(FR 2880278)

TYPE: Patent application

APPLICANT: Greentech SA. (France)

COUNTRY: France

DATE OF PUBLICATION: July 7, 2006

MAIN CLAIM:

Utilisation d’huile ou de protéines extraites de la graine de Plukenetia volubilitis Linneo, appelé communément Inca Inchi, pour la préparation d’un ingrédient actif entrant dans la composition de produits cosmétiques ou dermatologiques. [Use of oil or proteins extracted from the seeds of Plukenetia volubilis linneo, known commonly as “Inca Inchi”, for the preparation of an active ingredient present in the composition of cosmetic or dermatological products.]

PRIOR ART FOUND BY THE COMMISSION:

A publication in which it is stated that “the old Mayoruna, Chayuhuita, Campa, Huitoto, Shipibo, Yagua and Bora (indigenous peoples of the Peruvian Amazon) mix the oil of

Plukenetia volubilis with flour from this same kernel and prepare a special cream to revitalize and rejuvenate the skin” (“Especies Vegetales Promisorias de los Países del Convenio Andrés Bello”, 1992).

ACTION: A document was submitted to the National Intellectual Property Institute of France (INPI) requesting that the patent application be rejected due to lack of novelty. The documentation supporting the request was enclosed.

CURRENT STATUS: Application being assessed by INPI.

5. An extract of a plant belonging to the genus *Plukenetia volubilis* and its cosmetic use. (WO/2006/048158)

TYPE: Patent application

APPLICANT: Cognis France S.A.S (France)

PCT application

DATE OF PUBLICATION: May 11, 2006

MAIN CLAIMS:

1. A cosmetic use of an extract of a plant belonging to the family Euphorbiaceae (preferably belonging to the genus *Plukenetia*).
2. A cosmetic use of a protein or a mixture of proteins, whereby said protein or said mixture of proteins is extractable from a plant belonging to the family Euphorbiaceae (preferably belonging to the genus *Plukenetia*).

PRIOR ART FOUND BY THE COMMISSION:

A publication in which it is stated that “the old Mayoruna, Chayuhuita, Campa, Huitoto, Shipibo, Yagua and Bora (indigenous peoples of the Peruvian Amazon) mix the oil of *Plukenetia volubilis* with flour from this same kernel and prepare a special cream to revitalize and rejuvenate the skin” (“Especies Vegetales Promisorias de los Países del Convenio Andrés Bello”, 1992).

ACTION: The documents to submit comments when the application reaches the national phase are in the process of being prepared.

CURRENT STATUS: Application being assessed.

LIMITATIONS AND PROBLEMS FACED:

Some of the limitations and problems faced by the National Anti-Biopiracy Commission are detailed below.

1. In the majority of cases analyzed by the Commission no reference is made to the origin of the resource or knowledge, nor is it mentioned that such resource or knowledge were used to develop the invention.
2. Often, the description of what the applicant wishes to protect is not clear enough, or in other cases the description is ambiguous. This is the case where the applicant wishes to claim a product on the basis of at least one resource from a list of various possible resources, or when the resources are presented across a very wide range of proportions (between 0.001 and 99.9%).
3. There is a wealth of literature and information about resources of Peruvian origin, but access to such information is at times difficult. This explains why patent offices in foreign countries have not institutionalized the practice of revising documents and literature which could refer to ancestral uses of components of biological diversity by indigenous peoples or to different manifestations of indigenous traditional knowledge. These practical difficulties affect the possibilities for rigorous and comprehensive examinations of patent applications, giving rise, in many cases, to the granting of rights of doubtful legitimacy.
4. Even though in the majority of cases the database of the Japan Patent Office provides a literal translation into English of applications and/or patents, the translation is often inaccurate, which causes confusion and, at times, makes an analysis impossible; in some cases, the database permits access only to the original document published in Japanese (not offering the possibility of accessing the English translation of the claims), which prevents an analysis of the document, therefore making it necessary to use the services of a specialist translator, which is a situation that proves difficult for the National Commission to manage due to the costs that this entails in terms of time and money.
5. With regard to the application for a patent for the functional food product containing maca, although this application was rejected by the Japan Patent Office, the information that we sent in good time reporting the existence of prior art relevant to the claims was not taken into account in the analysis of the patentability requirements for the application concerned.
6. Guaranteeing the timely detection of cases of biopiracy such as those mentioned in this document would require resources which the Commission does not have at its disposal.
7. Each country has different rules concerning the possibility of third parties intervening in a patent application. Some country's legislation provides for the intervention of third parties only after the patent has been granted, which hinders the Commission's work enormously since it is much more difficult to act when it concerns a patent that has already been granted.
8. The situation is even more problematic when it concerns an international application under the PCT system, since this system does not provide for the possibility of opposing a patent when it is in the international phase.

CONCLUSIONS

Today, the biological diversity of Peru is one of the main pillars of its national economy by virtue of the fact that 99% of its fishing activities depend on the country's native hydrobiological resources, 65% of its agricultural production is based on native genetic resources, 95% of its livestock farming uses native natural pastures and 99% of its forestry industry uses native woodland and species. As a result, Peru's biodiversity is an important source of direct employment and livelihood for a large part of its population and is of vital importance to national culture, science and technology (CONAM, 1999).

The defensive protection of genetic resources and traditional knowledge is an extremely complex task for a country such as Peru whose territory has such broad biodiversity. However, such protection is necessary given that bad patents or potential bad patents can have a very detrimental effect on the economic, social and cultural interests of a country such as Peru. It is by no means a question of dismantling the patent system; it is simply a matter of achieving the objective of promoting innovation whilst maintaining a degree of fairness and equity among the stakeholders involved in the system.

The patent system as it operates today results, in many cases, in inventions generated, directly or indirectly, from genetic resources of Peruvian origin or from the traditional knowledge of its communities, passing the examinations of novelty or inventive step when they should not. Moreover, it is not taken into account that those resources or traditional knowledge may have been obtained in an irregular or overtly illegal manner. This is particularly true of Peru, which has had a regime for access to genetic resources and another for protection of traditional knowledge in force for a number of years.

The patent system works only if the rights of those who made the invention possible are acknowledged. The system does not work (or at least does not work as it should) if it acknowledges only the rights of those who have achieved an invention using the materials developed by others, thereby infringing their rights.

There is an urgent need to rethink the patent system and to consider how to make it more balanced. The current intellectual property system does little to ensure fair and equitable compensation for benefits derived from the use of genetic resources and traditional knowledge. Although it is true that the patent system does not have the function of guaranteeing compensation for benefits and regulated access to genetic resources, it is necessary to create synergies between these needs and the functionality of the system in order to make it a fairer system.

The measures taken at the national level are not enough. There is a need for regulations and obligations at the international level to guarantee the incorporation, implementation and fulfillment of these requirements. In this regard, we consider it appropriate for international agreements to include the requirement that a patent applicant for an invention containing, directly or indirectly, biological resources or traditional knowledge, disclose the source and country of origin of the resource or knowledge used in the invention, as well as proof of the legal access to such resource or knowledge. This is necessary to prevent biopiracy and to avoid bad patents. This position has been demonstrated in multiple declarations and interventions (individually or in conjunction with countries with similar interests) in various fora, in particular in the WTO, by Peru and by many other countries such as Brazil, India, Thailand, Colombia and China.

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