

ICTSD Project on Genetic Resources



The Disclosure of Origin Requirement in Central America



Legal Texts, Practical Experience and Implementation Challenges

By Jorge Cabrera Medaglia, Costa Rica's National Biodiversity Institute and Centre for International Sustainable Development Law



International Centre for Trade and Sustainable Development

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Legal Texts, Practical Experience and Implementation
Challenges

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TABLE OF CONTENT

ABBREVIATIONS AND ACRONYMS	iv
LIST OF TABLES	v
FOREWORD	vi
1. INTRODUCTION	1
2. DISCLOSURE OF ORIGIN IN IPR APPLICATIONS – PRELIMINARY CONSIDERATIONS	2
2.1 The Work of the CBD	2
2.2 The Main Elements of the Proposal	3
3. CENTRAL AMERICA EXPERIENCE	7
3.1 Costa Rican Legal Framework	7
3.2 Panama’s Access Legislation	9
4. DISCLOSURE OF ORIGIN AND FREE TRADE AGREEMENTS (FTAS)	13
4.1 The Biodiversity Law (LB) Amendment	13
5. RECOMMENDATIONS	15
ENDNOTES	16
REFERENCES	19
ANNEX 1	20

ABBREVIATIONS AND ACRONYMS

ABS	Access To Genetic Resources And Benefit Sharing
CBD	Convention On Biological Diversity
COP	Conference Of The Parties To The Cbd
GR	Genetic resources
IGC	Intergovernmental Committee On Genetic Resources And Intellectual Property Rights; Traditional Knowledge And Folklore
IT	International Treaty On Plant Genetic Resources For Food And Agriculture Of The Fao
IPR	Intellectual Property Rights
IR	International Regime On Access To Genetic Resources And Benefit Sharing
MAT	Mutually Agreed Terms
PIC	Prior Informed Consent
PBR	Plant Breeders' Rights
TEG	Technical Expert Group Of The Cbd
TT	Technology Transfer
TK	Traditional Knowledge
TRIPS	Wto Agreement On Trade-Related Aspects Of Intellectual Property Rights
UPOV	The International Union For The Protection Of New Varieties Of Plants
WG ABS	Working Group On Access To Genetic Resources And Benefit Sharing
WIPO	World Intellectual Property Organisation
WTO	World Trade Organisation

LIST OF TABLES

Table 1 Disclosure of origin in patent applications

Table 2 UPOV Council position on ABS

FOREWORD

Loss of biological diversity - understood as our biosphere's total endowment of living organisms, their genetic variation and functions and the ecosystems of which they are a part of - stands, alongside climate change, as one of the most pressing and daunting global challenges of our times. The increasingly rapid and massive rates of deterioration and loss of environmental resources and functions have brought an acute awareness of the urgent need for effective policies and mechanisms to ensure these valuable resources are used sustainably; this is an imperative beyond moral and ethical concerns that cannot be further postponed as societies become clearer about biodiversity's critical role in human well-being, global economic development and poverty reduction.

Diversity in nature is the key to the natural regulation of global climate and the equilibrium in the gaseous composition of our atmosphere. This diversity is the essence of healthy soils; it allows for natural regeneration and recycling of nutrients, and the maintenance of a biological balance between destructive and useful plants and organisms. It enables the existence of waterways, watersheds and aquifers and allows marine life and environments to thrive. Furthermore, diversity in natural resources forms the cornerstone of strategic and pivotal industries in critical areas of economic activity for the provision of food, health, energy and fuels, clothing, and shelter. In addition, biodiversity has proven to be critical in advancements on waste treatment, environmental services and the venturing into the new frontiers of nanotechnology, and geoengineering.

Diversity of living organisms is dwindling at a much faster pace than generally realized. Not only species are disappearing, we now know for certain that their genetic richness and functions are also dramatically affected by changes in ecosystems. Even though alterations to our natural stock through either innate biophysical causes (such as natural processes and disasters) or human activity has been a characteristic of the world throughout its existence, destruction and change now occurs on a much greater magnitude and scale, and in exceptional ways. Propelled by an explosion in economic activity, ever-increasing demand and global integration of economies, impacts on diversity of living organisms are also more rapid and of major reach across ecosystems and regions.

In order to better grasp the enormity of the problem and our passion for it at ICTSD, allow me to quote one of the pioneers of our understanding of the diversity of life, Professor E.O. Wilson from Harvard University, when he states: "Almost all current biodiversity analysts agree that the extinction of species is proceeding at one hundred to 10,000 times the pre-human rate, while the rate of origin of new species is decreasing. [...] Each species is the repository of an immense amount of genetic information. The number of genes range from about 1,000 in bacteria and 10,000 in some fungi to 400,000 or more in many flowering plants and a few animals. A typical mammal such as the house mouse (*Mus musculus*) has about 100,000 genes. This full complement is found in each of its myriad cells, organized from four strings of DNA, each of which comprises about a billion nucleotide pairs..."

Concluded at the earth summit (1992), the United Nations Convention on Biological Diversity (CBD) acknowledges this important reality when underlining the "intrinsic ecological, genetic, social, economic, scientific, educational, cultural, recreational and aesthetic value" of biodiversity. Unlike former and other multilateral environmental agreements, it addresses global biodiversity as a whole rather than limiting itself to certain ecosystems, species, or forms of biological diversity.

Premised on a global strategy for sustainable development, the CBD recognizes the sovereign rights of States over their natural resources and pursues three objectives: 1) the conservation of biological diversity, 2) the sustainable use of its components and 3) the fair and equitable sharing of the benefits arising out of the utilization of genetic resources and associated traditional knowledge.

The realization of these objectives has faced immense challenges. The third objective in particular - fair and equitable sharing of benefits arising out of the use of genetic resources - has proven difficult to implement in an effective manner, as the use of genetic resources is increasingly linked with international trade. Users of genetic resources, such as individuals and firms that develop innovative applications based on such resources, often are located outside the country of origin of these resources.

In addition, only relatively recently have countries, mostly developing ones, started to implement domestic rules that provide for access and benefit sharing. In contrast, many developed countries - where pharmaceutical, biotechnological and agricultural companies, have their headquarters - have not put in place corresponding regulations in order to ensure benefit sharing.

In this context, well known cases of misappropriation of genetic resources and associated traditional knowledge during the past two decades have crystallized the tensions between CBD objectives of promoting the fair and equitable sharing of benefits and the types of incentives established by trade and intellectual property rules, in particular those of the World Trade Organization (WTO) Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS). While measures such as the disclosure of origin requirement, certificates of compliance and geographical indications related to trade in genetic resources and associated traditional knowledge have been introduced in domestic legislations in recent years to prevent such misappropriation, they still raise critical questions for all the actors involved.

Against this backdrop, following protracted negotiations and a critical political underwriting of all UN members at the 2002 Johannesburg Summit on Sustainable Development, the CBD Conference of the Parties (COP) mandated, in 2004, the Working Group on access and benefit sharing (ABS) to negotiate an international regime (IR) on ABS. The aim of the IR is focussed on adopting an instrument(s) to effectively implement the objectives of the convention and its relevant provisions (Article 15 on access to genetic resources and Article 8(j) on traditional knowledge). In 2008, the COP instructed the Working Group to finalize the negotiation of the IR before its tenth meeting, in 2010, in Japan.

The negotiations of the IR took place amid an extraordinarily complex global landscape where a profusion of fora - such as the WTO, the World Intellectual Property Organization (WIPO), the Food and Agricultural Organization (FAO) and the Union for International Protection of New Varieties of Plants (UPOV) - address issues relating to the sustainable use of genetic resources according to their respective mandates. While countries reaffirm the need to ensure consistency between deliberations and outcomes in these different fora, they tend to disagree on how such consistency is to be achieved.

At the WTO, an increasingly large number of countries are arguing that in order to ensure there is consistency between the specific provisions of the CBD and the patent provisions under the TRIPS agreement, an amendment to TRIPS should be introduced. This proposed adjustment would require the disclosure of origin of genetic resources in patent applications as evidence of 'prior informed consent' and 'equitable benefit sharing'.

Countries that oppose such measure at the WTO favour discussions at the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore

(IGC) of WIPO, which was established in 2001. After several years of deliberations with little progress in terms of norm-setting, the IGC was finally provided in 2009 with an explicit mandate to undertake “text-based negotiations with the objective of reaching agreement on a text of an international legal instrument (or instruments) which will ensure the effective protection of genetic resources, traditional knowledge and the protection of traditional cultural expressions.”

Countries which oppose discussions on intellectual property aspects in the context of the negotiations of the IR often invoke this new IGC mandate arguing that WIPO is the appropriate forum to address these aspects.

Despite these ‘forum-shifting’ strategies and the fact that few tangible advances have ultimately been made in several of these fora, the terms of the debate have significantly evolved in recent years. Many developing countries, now better aware of the multifaceted relevance of their biodiversity, are factoring its valuation into their economic strategies. Furthermore, all stakeholders have also come to recognize the complexity of the issues at hand and that there is no single ‘magic’ solution that would ensure effective ‘equitable benefit sharing’; but rather a variety of complementary measures to be pursued at the national, regional and international levels. Drawing lessons from national and regional experiences on ABS implementation can benefit international discussions. Virtually all countries agree on the need to diffuse potential tensions between the biodiversity, trade and intellectual property regimes, though disagreements persist on the most appropriate means to do so.

Since its establishment in 1996, the International Centre for Trade and Sustainable Development (ICTSD) has been working on these issues from various angles and perspectives, following and participating in the process that brought upon the system in place today: from Rio to Johannesburg, from Bonn to Geneva. As a non-partisan actor, it has generated sound and novel analysis on viable and sustainable policy options and convened exchange between a wide range of stakeholders from developing and developed countries alike.

In 2009, the German Development Agency (GTZ) and ICTSD undertook a collaborative initiative to create regional platforms for interactive and generative dialogue among key actors. The collaboration focused on problem-solving and consensus-building in regards to biodiversity issues with a high priority in development and environmental policies in Central and South America. As part of this project, in coordination with local partners, ICTSD and GTZ jointly organised two regional dialogues in Costa Rica and Peru bringing together international experts to explore concerns, knowledge gaps and priority areas for action at the political and technical level on the interface between intellectual property rights and the sustainable use of biological resources.

Almost two decades after the conclusion of the CBD a number of countries have made critical advances in design and implementation of domestic mechanisms that address these concerns. To bring their view to the international level and to analyse their experiences will be critical for the successful conclusion of multilateral processes. As we now move towards the Tenth Conference of the Parties (COP 10) to the CBD in Nagoya in October 2010, there is indeed an urgent need for deepening efforts to provide sound analysis on pressing systemic challenges and flaws, domestic and regional experiences, needs and abilities, and potential political and technical solutions.

This issue paper - published by ICTSD’s project on Genetic Resources - is one of several outcomes generated during the 2009-2010 dialogue series; it builds on, and is complemented by, ICTSD work through its various related projects. The paper aims to contribute to this discussion by

presenting the legal framework on access and benefit sharing in Central American countries, as well as practical experiences with regard to the disclosure of origin and certificate of compliance for the purposes of access and benefit sharing in intellectual property rights applications. The paper starts by presenting some conceptual considerations on this mechanism. It then outlines the main legal and administrative aspects of the disclosure of origin requirement in Costa Rican and Panamanian national laws and highlights experiences regarding their implementation. Finally, it suggests some ways to improve the drafting and implementation process in national legislation with regards to this mechanism. By presenting research on concrete regional experiences at a stage where negotiations gain momentum, we aim to inform involved stakeholders so as to allow them to consider options and approaches that will support the adoption of an efficient ABS system.

We hope that you will find this paper stimulating and useful for your work.

We hope that you will find this paper a stimulating and useful contribution to the ongoing debate and negotiations on an international regime for access and benefit sharing of genetic resources.



Ricardo Meléndez-Ortiz
Chief Executive, ICTSD

1. INTRODUCTION

This paper presents Central America's legal framework and practical experience with regard to the disclosure of origin and the certificate of compliance in IPR application, particularly in cases involving patents.¹

The paper starts by presenting some theoretical considerations on this mechanism. It then outlines the main legal and administrative aspects of the disclosure of origin requirement

in Costa Rican and Panamanian national laws, and discusses the actual experiences and challenges that arose from their implementation. Moreover, the paper analyses the impact of Free Trade Agreements on the disclosure of origin and biodiversity related provisions in Costa Rican law. Finally, it suggests some recommendations on how to improve the drafting and implementation process of national legislation regarding this instrument.

2. DISCLOSURE OF ORIGIN IN IPR APPLICATIONS – PRELIMINARY CONSIDERATIONS

2.1 The Work of the CBD

One of the first measures suggested in order to achieve a synergistic relationship between the CBD and intellectual property systems (in particular, the WTO/TRIPs) was the disclosure of the origin of genetic resources or associated traditional knowledge in intellectual property right (IPR) applications, particularly in patents. For several years the CBD, the WTO, the WIPO, and numerous activities and reports have insisted upon the need to promote disclosure of origin in IPR applications.²

The Conferences of the Parties to the Convention (COP) have also addressed the relationship between IPR and biodiversity. For example, at the III Conference of the Parties, Decision III-15 (access to genetic resources) requested that the Executive Secretary cooperate with the WTO through its Committee on Trade and Environment, in order to explore the extent of the potential links between Article 15 of the Convention and the TRIPs. Decision III-17 also recognised, among other things, that further research is required in order to understand the relationship between the provisions of the TRIPs and the CBD, particularly those points relating to technology transfer, the conservation and sustainable use of biodiversity, fair and equitable benefit-sharing, protection of traditional knowledge.

The IV Conference of the Parties (1999 Bratislava), in addition to reiterating a number of previous calls from past COPs, emphasised the need to ensure consistency in the implementation of the Convention and the TRIPs. This consistency would be instrumental in increasing mutual supportiveness between both regimes and ensuring that biodiversity-related concerns receive IPR protection (IV-15).

The V Conference (2000, Kenya), in Decision V-26, requested that the WIPO and UPOV

properly take into account the relevant provisions of the Convention in their work, including the impact IPR might have on the conservation and sustainable use of biological diversity, and particularly on the value of traditional knowledge. Subsequently, it invited the WTO to bear in mind that the TRIPs and the CBD are mutually related, and called for a more in-depth exploration of that mutually supportive relationship.

Resolution VI/24/C 1, “The Role of IPR in the Implementation of Benefit-Sharing Agreements,” invited the governments and Parties to promote disclosure of the origin of genetic resources in IPR applications when the protected material consists of or uses genetic resources in its development. The aim of this disclosure is to help track compliance with prior informed consent and the mutually agreed upon conditions on which access to those resources was granted. Numeral 2 contains the same invitation regarding associated traditional knowledge.

At the VII Conference of the Parties, Decision VII/ 19 requested that the WGABS identify aspects related to disclosure of the origin of genetic resources and associated traditional knowledge in IPR applications, including aspects related to the certificate of origin/source/legal provenance. It also asked the WIPO and UNCTAD to prepare studies on disclosure of origin in IPR applications

As stated, various decisions of the Conferences of the Parties to the CBD have mentioned disclosure of origin, at least since the COP IV. The Bonn Guidelines also refer to this topic when they indicate that user countries should take into account measures to promote disclosure of the origin of genetic resources and the origin of knowledge, innovations, and practices in IPR applications (16.d.ii).

2.2 The Main Elements of the Proposal

It is not surprising that the requirement for disclosure of origin and proof of legality of access in IPR applications has been the object of intense political and legal debate. Although different legislations contain references to this requirement, they differ in terms of their consequences.³ Some of the biodiversity or intellectual property laws of several countries include the obligation to disclose the origin of genetic material utilised in inventions or plant varieties a period. In some cases, laws require proof of the existence of prior informed consent (PIC) or a certificate or even to present proof of the existence of prior informed consent, or a certificate of origin that establishes the legality of access to the genetic material or associated traditional knowledge. This stipulation would help to support compliance with the CBD provisions on access to genetic resources and benefit-sharing.

In most cases, the European laws that have introduced this requirement have referred only to the obligation to disclose the origin of or, in the case of Norway, to prove the existence of PIC. However, these laws do not affect the existence of intellectual property rights as such, but rather fall within the penal or civil domains. Few laws on plant breeders' rights (e.g India, Ecuador, Peru), consider this requirement.

As Correa states, "If the purpose of this obligation and its rationale seem sufficiently clear, and considerable - though not unanimous - support exists for its establishment, the conditions and circumstances of this obligation and how it will be applied need then to be more precisely defined... The scope and conditions of the obligation's application should be consistent with its purpose, taking care not to impose a disproportionate burden on the applicants and the institutions in charge of their applications."⁴

From a technical point of view, progress needs to be made in defining a series of elements that will determine the way that disclosure would work, particularly if this instrument is to become a practical tool.⁵ These elements include:

- What information should be divulged? Would genetic or biological resources (or both) and their associated traditional knowledge be the object of disclosure?
- What is the meaning of origin? Does the origin refer to the resource's country of origin or to its source, i.e. the country from which the resource was received? Or does the origin refer to the country that contributes or provides the resource's geographic origin? Does origin refer to combination of different options, such as the disclosure of the source together with, if known, the resource's country of origin.
- What kind of information or documentation should be submitted? Whether the mere disclosure of information would be sufficient to comply with the requirement; or should the application be accompanied by a declaration from the applicant; or by some form of documented evidence to prove compliance with access laws, such as a copy of the access contract or another authorising document.
- How should the information be presented? Should standardised terminology and certain specific content, etc. be used?
- How should the relationship between biological/genetic resources, associated traditional knowledge, and the actual invention be determined? For example, if they form part of the material for which intellectual property rights are requested; if they have been used in the process of developing the invention; if they have been used to facilitate the development of the material to be protected; if they constitute the necessary antecedent for that material, etc.
- When should access to resources or knowledge be considered to have been duly authorised?
- When will the information be examined, and by whom?

- What should the consequences be for non-compliance, including civil or penal liabilities? Should these involve the application of provisions on unfair competition; administrative sanctions; suspension of application processing; revocation or annulment of rights when the submitted information is insufficient or false; the requirement that patent rights be transferred either partially or completely if their purpose was to ensure fair benefit sharing; the requirement that any benefits received be repaid, etc.?

Other aspects that should be taken into account when considering the inclusion of disclosure in the International Regimen (ABS Protocol) or in national laws are as follows:⁶

- The instrument has a limited impact on the prevention of misappropriation or biopiracy, and should therefore be accompanied by other complementary mechanisms. For example, in a number of documented cases of misappropriation through patents, the geographical origin of the resource was mentioned. In order to improve the quality of the granting of patents and other intellectual property rights, complementary mechanisms are required, such as improvements in search systems in order to determine if the inventions are novel. These complementary mechanisms have been explored by the WIPO Intergovernmental Committee on Genetic Resources and Intellectual Property, Traditional Knowledge and Folklore.
- Whether the countries involved have the ability to effectively monitor patent applications and patents granted should also be considered, in order to determine whether there has been misappropriation of materials. Even if misappropriation is detected, it is doubtful that the countries have the economic and financial capacity to invalidate patents in foreign jurisdictions, considering the long and costly process involved. This situation points once again to the need to study the measures of other user countries, such as those that facilitate access to justice, as required to achieve the objectives of the CBD.
- One way to prevent misappropriation is to improve access to information existing in the public domain, and make it available to the technical staff in charge of reviewing patents to aid them in determining if they are novel and if prior art exists. This is one of the aspects the WIPO has been working on through the Intergovernmental Committee.
- Finally, although these provisions have been included in some countries' patent laws or in their biodiversity or related laws, it is also advisable, strictly at a national level, for the countries to begin introducing a new statutory obligation into their access or related laws. More specifically, access applicants should be required to disclose the origin or source of the resource at the time access is granted, if the access applicant presents a patent application. Although it is not possible to categorically state whether or how the patent offices will take these legal or contractual provisions into account, or whether they will take action against an applicant that does not comply with them, this measure still merits consideration.
- Incorporating this provision will require that actions be taken at a national level, rather than waiting for the conclusion of international negotiations on the Regime or the WTO discussions. Disclosure of origin would make it possible, among other things, to prevent misappropriation of genetic resources and associated traditional knowledge. Thus, it would not only be a transparency measure for the granting of IPR, but also a defensive measure aimed at protecting traditional knowledge against misappropriation or irregular appropriation.

Table 1: Disclosure of Origin in IPR

Although the idea of disclosure of origin/evidence of prior informed consent/evidence of benefit-sharing has mainly been discussed within the context of patent systems, it is also applicable - when taking technical differences into account - to plant variety systems and to approval processes in general.

The objectives of the proposal are:⁷

1. **Transparency:** To allow national authorities that grant access to genetic resources to track the use of these resources in patent applications and deeds.
2. **Compliance with access conditions:** To make it possible to track compliance with prior informed consent and the mutually agreed upon conditions on which access was granted.
3. **Determination of prior art:** The disclosure would allow Patent Offices to better analyse novelty and the level of inventiveness.
4. **Relationship between the TRIPs Agreement and the CBD:** Disclosure of origin would help prevent conflicts between the TRIPs Agreement and the CBD, and would support their mutual implementation.
5. **Biopiracy:** Disclosure would stop biopiracy or the misappropriation of genetic resources or traditional knowledge resulting from the granting of “bad patents.”

In the case of plant varieties, the UPOV Convention (Act of 1991) specifically establishes that the requirements to grant or cancel a plant breeder right shall not differ from those stipulated by the UPOV (See chart No. 2). It expressly states that plant breeders' rights shall not be subject to further conditions (Article 5), provided that national formalities have been complied with and the required fees have been paid. It also stipulates that the rights shall not be cancelled or annulled for reasons other than those indicated in Articles 21 and 22. It should be noted that the UPOV has mentioned that it is not opposed to disclosure that facilitates the examination of the material, but that it will not consider such disclosure a requirement or an additional condition for protection.

It is therefore important, first, to emphasize that article 5 expressly stipulates that plant breeders' rights shall be subject to each country's formalities. Consequently, it is legally possible to establish disclosure of origin as a formal but non-substantive requirement. If this requirement is not met, the application will not be processed.

Secondly, the case of false disclosures of origin should be considered. In countries where the disclosure requirement has been applied, two possible solutions have been adopted: the annulment or cancellation of the patent (India, Brazil, the Andean Community, etc.) or penal, administrative or civil sanctions outside patent law (European countries such as Norway, Denmark, Belgium and Sweden).

Thirdly, it is important to consider the details concerning the origin of plant varieties and the extent to which disclosure of origin would safeguard the legality of access to the material, whether its origin is national or foreign - the latter being more likely in the case of imported materials.

In the case of plant varieties, there may be technical and practical obstacles to this provision unless it is carefully structured. Different objections have been raised regarding the applicability of disclosure to plant varieties, such as: problems that occur when plant varieties originate from different countries and from crosses and back-crosses; obstacles to

determining the origin of a variety's germplasm, which can originate from a combination of genes from different countries; the impracticality of stipulating benefits, given that the origins of plant varieties can be traced to different countries and communities, unlike pharmaceutical products, which can be derived or moulded from a single natural component; etc.

Table 2: Position of the UPOV Council on Access to Genetic Resources and Benefit-sharing Related to PBR (Adopted by the UPOV Council in its Session number 37, on 23 October 2003)

Access to genetic resources: Access to genetic resources is essential so that progress can be made in the area of plant breeding. The plant breeders' exemption reflects the position that the worldwide plant breeder community requires access to all kinds of materials in order to make the best possible progress in the area of plant breeding and thus maximise the use of genetic resources for the benefit of society.

Disclosure of origin: Plant breeders must usually provide information on the genetic origin of the plant variety on the technical questionnaire that accompanies the application for protection. When UPOV examines the variety, it encourages the provision of information on the origin of the genetic material used in creating it, but it does not accept disclosure of origin as an additional condition for protection. The Convention requires protection for varieties that are novel, homogeneous, stable, distinct and designated by a denomination, and does not admit additional requirements. In some cases, it can be impractical or difficult to identify the exact origin of the genetic material used. Disclosure of origin should not be introduced as a condition for the protection of varieties, although it may be included in separate laws.

Prior Informed Consent: UPOV promotes the principle of transparency and ethical behaviour regarding the legality of access to genetic resources, including proof of prior informed consent. Consequently, access to genetic material must be carried out in accordance with the legal framework of the country of origin. However, the Convention requires that plant breeders' rights not be subject to any additional condition other than those required for protection (article 5 of the UPOV, 1991). In addition, the competent authorities are not considered to be in the best position to verify whether access to the genetic resource has taken place in accordance with the applicable legislation of the country of origin of the resource.

Benefit-sharing: UPOV would be concerned if mechanisms were established to ensure the sharing of benefits arising out of access to the phylogenetic resources used in a new plant variety. This obligation would even be incompatible with the plant breeder exemption, which does not require acts of improvement carried out on other varieties to be subject to restrictions. Also, in such cases, the holders of the initial varieties are not entitled to any compensation, except in the case of varieties that are, essentially, derived. This requirement might lead plant breeders to stop trying to protect or develop their varieties.

Subsistence Farmers: The UPOV contains an exemption that allows for non-commercial and private actions to be carried out, since they are excluded from the scope of breeders' rights.

Re-use of Seeds: The re-use of seeds is an optional mechanism for the benefit-sharing stipulated by the Convention. However, this provision is subject to reasonable limits and requires the safeguarding of the breeder's legitimate interests. For example, some countries only apply the exemption to certain species, or they limit its application according to the size of the property or production level.

Access and PBR: The laws on access to genetic resources and plant breeder rights have different objectives and scopes of application, and require different structures to administer and monitor them. Therefore, it is considered appropriate to include them in different legislation, although the regulations must be compatible and mutually supportive.

3. CENTRAL AMERICA EXPERIENCE

ABS is relatively a new legal issue in Central America, with the exception of Costa Rica. Only a few of the countries (Costa Rica, Panama) have access laws, and some are only in the initial phases of implementation (Panama). However, several of them have draft legislation (Nicaragua) or initiatives that are in the process (El Salvador, Guatemala) for the development of modern legal frameworks to regulate ABS. This information is summarised in the Annex table.

3.1. Costa Rican Legal Framework

Costa Rica's Biodiversity Law (BL) of 27 May 1998 applies to the components of biodiversity that are under the sovereignty of the State, as well as to the processes and activities carried out under its jurisdiction or control, independent from those effects manifested inside or outside national jurisdiction. This Law specifically regulates the use and management of the components of biodiversity, as well as the associated knowledge, benefit-sharing and derived costs from this utilisation.

Article 6 establishes that the biochemical and genetic properties of the components of wild or domesticated biodiversity are part of the public domain. The State authorises the exploration, research, bioprospecting and use of biodiversity components that constitute part of public domain, as well as the use of all genetic and biochemical resources, through access standards established in Chapter V of the Law.

Likewise, in accordance with Articles 62 and 69, all research or bioprospecting programs on the genetic or biochemical material of biodiversity that are to be carried out in Costa Rican territory require an access permit, unless they fall into one of the exceptions provided by Article 4 of the Law. These exceptions include: (1) access to human genetic resources; (2) the non-profit exchange

of genetic and biochemical resources and traditional knowledge; (3) research by public universities, which had one year, ending in May 1999, to establish independent controls and regulations for non-profit access to biodiversity. If none of these exceptions apply, all sectors (pharmaceuticals, agriculture, crop protection, biotechnology, ornamental, herbal, etc.) that wish to access genetic components are subject to the Law and must follow the access procedures. The definitions of access and bioprospecting in the Law also restrict the Law's scope.

The access regulations apply to genetic resources in public or private lands, terrestrial or marine environments, under *ex situ* or *in situ* conditions and in indigenous territories. In addition, the rules of indigenous people should be taken into account for access in their territories, as should their *sui generis* community intellectual rights. Similarly, it is recognised that communities and indigenous peoples have the right to deny access to their resources and associated knowledge for cultural, spiritual, economic or other reasons.

The access procedure is set out in two chapters of the BL. The competent body that grants access in the first place is the Technical Office (TO) of the National Biodiversity Commission (CONAGEBIO) within the Ministry of Environment, Energy and Telecommunications (MEET). CONAGEBIO is entrusted with preparing access and benefit-sharing policies, and can revoke the rulings of the TO on access issues. The main duty of the TO is to process, reject, and monitor access applications; and coordinate with the Conservation Areas, indigenous peoples, peasant communities and the private sector on actions relating to access. It is responsible for organising and updating a register of access applications to the components of biodiversity, *ex situ* collections and the natural and legal persons who work on genetic manipulations.

Chapter V defines the requirements and procedures to access genetic and biochemical components and the protection of the associated knowledge. CONAGEBIO is expected to act as the mandatory consultative body for all application procedures involving the protection of intellectual rights related to biodiversity. The Law regulates the basic requirements for access, which include PIC, benefit-sharing, the protection of associated knowledge and the way in which the activities will contribute to conservation. Chapter V also establishes the legal procedures to be followed, the registry of access rights and the protection of confidential information.

The BL regulates the terms of access permits, including their limitations and characteristics; the information required in a permit application; the authorisation of agreements with individuals seeking access to genetic and biochemical components by the Technical Office; and the possibility of agreements with universities and other duly registered centres. It stipulates that up to 10 percent of the royalties must go to the conservation area, private owner or indigenous territory, in addition to the payment of administrative expenses. Also, the Technical Office must always be consulted in processes where IPRs are granted for components of biodiversity, and its decision on these matters is binding.⁸

Lastly, the BL establishes the grounds for the protection of traditional, indigenous and community knowledge, and for the establishment of a participatory process for the determination and registration of these *sui generis* intellectual community rights. Article 112 establishes a system of fines for illegal access, with a section on the framework for sanctions.

During the process of drafting the LB and, as part of the definition of regulations on access and benefit-sharing, the issue of IPRs and their relationship with biodiversity inevitably arose.

Thus, the LB establishes that intellectual property rights shall be congruent with the

Law's objectives by virtue of the principle of integration (Article 79). The Law originally excluded the following: DNA sequences from patent processes; plants and animals; unmodified microorganisms; essential biological processes for plant and animal production; the processes of nature or natural cycles; inventions essentially derived from the knowledge of traditional biological practices or in the public domain; and inventions that are produced monopolistically that may affect the processes or basic agricultural products used for food and health purposes (Article 78).

However, this article was modified by an amendment of an IPR Law⁹ which was enacted to comply with the IPR commitments of the Free Trade Agreement between Central America, Dominican Republic and the United States (CAFTA-DR). This amendment excluded the following things from patent protection: DNA and RNA sequences to the extent they do not fulfil the patent requirements; microorganisms as they are found in nature; processes for the production of plants and animals that are essentially biological, with the exception of non-biological or microbiological processes; and those inventions whose commercial exploitation must be prevented in order to protect the public order, morality, the health or life of human beings, animals and plants, and to prevent serious damages to the environment.

Authorities should consult the TO before granting protection of intellectual or industrial property-related innovations that involve biodiversity elements. The submission of the certificate of origin and prior informed consent shall be required. A well-grounded opposition by the TO shall prevent protection from being granted (Article 80).¹⁰ It has been stated that particular beneficiaries granted protection of intellectual or industrial property rights regarding biodiversity must cede to the State a legal obligatory license. In the event of a justified emergency, this license will allow the use of such rights for the benefit of the community. This provision is aimed at solving

an emergency, without involving compensation or royalty payment (Article 81).¹¹

In the case of regulation *ex situ*, Article 10 (export and certificate of legal provenance) is particularly relevant, and states that the permit does not exonerate the interested party from complying with the requirements for exporting live materials. In the case that materials must be exported, the interested party must request the **certificate of legal provenance**, which should always be attached to the material. This will be issued on the terms established by Article 19 of the *in situ* Access Regulation, and the office will have no more than 15 consecutive days to issue it after it is requested.

Intellectual property legislation

Costa Rica was the last country in the region to ratify the Free Trade Agreement with Central America, the Dominican Republic and the United States¹² (CAFTA-DR).

The Invention Patents Law, No. 6867, from 5 April 1983, and its amendments, establishes as patentable all creations derived from human intellect which can be applied in industry. It can be a product, a machine, a tool or a manufacturing process (Article 1)

- The following will not be considered an invention:
 - a) Discoveries, scientific theories, mathematical methods and isolated computing programs.
 - b) Purely aesthetic creations, literary or artistic works.
 - c) Publicity or business plans, principles or economic methods and those related to purely mental, intellectual or gaming activities.
 - d) The juxtaposition of known inventions or mixture of known products, their variations in structure or use, dimensions

or materials, except when it relates to a combination or fusion that cannot function separately or when qualities or characteristic functions are modified to obtain an industrial result that is not obvious to a technician in that material.

- Plant varieties will have legal protection through a special law.
- The following cannot be patented:
 - a) Inventions whose commercial exploitation must necessarily and objectively be prevented in order to protect the public order, morality, health or life of persons or animals so as to preserve plants or avoid serious damage to the environment.
 - b) Diagnostic, therapeutic and surgical methods for the treatment of people or animals.
 - c) Plants and animals.¹³
 - d) Procedures that are essentially biological and used for the production of plants or animals.

The Biodiversity Law recognises the existence of the certificate of legal provenance in the case where national genetic resources are accessed, and requires the presentation of this certificate before the competent office in order to issue IP rights. Similarly, a consultation is required with the Technical Office of CONABEGIO in the cases of innovations based on biodiversity elements of Costa Rica. It should be noted that the presentation of the certificate guarantees that the access procedure was followed. This includes the negotiation of Prior Consent and the Sharing of Benefits.

Neither the Plant Variety Protection Law No. 8631- nor its regulations- expressly requires that the TO be consulted before a plant breeder's rights are issued. Protection exceptions are

made for wild plants that are not modified (Article 2). Likewise, all the varieties that are protected by community intellectual rights *sui generis*, will be included within the concept of “notoriously known variety.” This inclusion is regardless of whether those rights have been registered or not, in accordance with what is established in Articles 82 and 84 of the Biodiversity Law No. 7788, to the extent that the variety is adequately described and its existence can be verified (Article 4).

Implementation Status¹⁴

In order to coordinate with the Intellectual Property Registry, several meetings have been held between the Technical Office and the Registry, including a Workshop for Capacity Development in application of Article 80 of the Biodiversity Law, carried out on 6 August 2008. In attendance were representatives from the Registry, experts, members of CONAGEBIO and institutional employees of the organisations from which the Registry solicits technical support. After this opportunity, the examiners and other experts became well informed about the requirements of the BL, including how to proceed when an invention that is derived from or which has made use of GR is presented before the Registry.

Currently, the patent office usually relies on external substantive examiners, and the patent office’s lawyers carry out the formal exam.

To the present date, no patent applications have been identified that have made use of national genetic resources.

The challenges for the proper implementation of the Article 80 consultation requirement relate to the fact that the Registry is made up of specialised intellectual property lawyers that are not familiar with the Biodiversity Law. Another challenge is that this consultation is

carried out at the substantive review of the application, which delays the completion of the patent processing.

To the present date, there is only one patent application (file No. 7415), named “SUBSTITUTED PIRIDINONAS AS MODULATORIES OF P38 MAP KINASE,” which has been consulted upon by the TO. The summary is as follows:

“Formula 1 components and its acceptable pharmaceutical salts are described, within which R1, R2, R3, R4 and R5 are defined in this application. These components are useful for the treatment of illnesses and ailments caused by or exacerbated by p38 MAP kinase activity and/or FNT. Also described are pharmaceutical compositions that contain compounds, methods to prepare compounds and treatment methods that use the compounds.”¹⁵

The above application was informally sent - after the above-mentioned Workshop - to the TO for consultation. The Technical Office issued a letter of response which commented, among other points, that in the forms used by the Registry there is no indication of the responsibility of the applicant to disclose the origin of the materials used in the invention. However, the TO concluded that the strains of *N.meningitidis* originated from the United States, Germany and Holland. It also considered that the claims do not include any information that refers to the patenting of microorganisms, DNA sequences, nucleotides, and/or amino acids as are found in nature. Therefore, this patent application does not infringe upon what is stipulated in Article 78 LB.

Finally, the Technical Office staff periodically carries out searches in patent databases to identify possible use of national genetic resources in a foreign invention application or patent granted.

3.2 Panama's Access Legislation¹⁶

The General Environment Law No. 41 from 1 July 1998 mandates that the National Environmental Authority be the competent body, based on what is established in the present law and its regulation, to dictate norms, and to regulate and control the access and use of biogenetic resources in general, with the exception of human species, with respect to intellectual property rights. In order to fulfil this function, it will develop and introduce legal tools and/or economic mechanisms. The right to use natural resources does not grant its users the right to use genetic resources contained in them (Article 72).

This article served as the starting point for the subsequent regulation on ABS.

Panama's Law No. 41 (Article 2) defines genetic resources as "a set of hereditary molecules within organisms whose primary function is the generational transfer of the information on natural heredity of live organisms. Its expression is the collection of cells and tissues that form the live organism." Similarly, it defines biological surveying as "[t]he exploration of wild natural areas in the search of species, genes or chemical substances derived from biological resources with the goal of obtaining medicinal, biotechnological and other products".

Article 62 of Law 41 states that natural resources are of the public domain and of social interest, as long as they do not infringe upon the rights legitimately acquired by individuals.

Article 63 of Law 41 stipulates that "indigenous territories (*comarcas*), and the municipalities where natural resources exist and are used or extracted, have the responsibility of contributing to their protection and conservation according to the parameters established by the National Environmental Authority, together with the indigenous authorities, in conformity with applicable law."

Executive Decree No. 257 from 16 October 2006 develops the provision of Article 71 of Law 41 and regulates access to genetic resources.

This Decree was subsequently amended by Decree No. 25 from 29 April 2009.

The Decree contains two issues of interest:

- a) The certificate of origin or provenance should be defined as "the legal recognition on the part of the National Environmental Authority of the origin or provenance of the genetic or biological resource whose genetic heredity makes up the genetic materials from where processes or other products are derived" (Article 3).
- b) Access contracts should include the obligation of the applicant to declare the origin and provenance of the genetic resources in all the publications or summaries that incorporate the genetic or biological resources collected (Article 19, paragraph e). In the same manner, the certificate of origin and provenance for the genetic and/or biological resource or material used in the development of the invention should be presented in all invention patent applications that are taken to the General Office of Intellectual Property and/or any patent office of WIPO member countries (Article 19, paragraph g).

The Genetic Resources Access Unit or Department (*Unidad de Acceso al Recurso Genético -UNARGEN*) was created; it will be ascribed to the National Office for Protected Areas and Wildlife of the National Environmental Authority. Through resolution AG-0208-2007, the Genetic Resources Access UNIT was further regulated and it will have, among other functions, the responsibility of processing all of the biological and genetic resource access applications (commercial, industrial and non-commercial). The Genetic and Biological Resources Access Unit has a staff team (close to 8 persons), an office and an assigned vehicle.

Relevant intellectual property legislation

The Free Trade Agreement with the United States, which has not been approved by the US Congress, obligates Panama to adhere to UPOV 9.

Panamanian legislation on patents, Law No. 35 from 10 May 1996, expressly exempts from patentability (Article 15):¹⁷

- 1) Essentially biological cases for the reproduction of plants, animals or their varieties when the General Office for Intellectual Property (*Dirección General de la Propiedad Industrial* -DIGERPI) of the Ministry of Commerce determines that they threaten the morality, integrity or dignity of human beings.
- 2) Plant species and animal species and breeds.
- 3) Plant varieties.

The exclusion of plant varieties is evident, even in a reiterative and confusing manner.

A PVP Law - based on the UPOV Convention - was enacted (Law 23 published in *La Gaceta* on 26 July 1997).¹⁸ A Registry of Protected Varieties under the charge of DIGERPI was created.

Lastly, Panama has a Law No. 20 from 26 June 2000 on the "Special regimen of collective rights for indigenous communities" and its regulation (Executive Decree No. 12 from 20 March 2001). A *sui generis* system was created for the protection of traditional knowledge, limited to indigenous communities and targeted fundamentally to folklore and other traditional cultural expressions. Intellectual property rights and indigenous community traditional knowledge on their creations such as dress, work instruments, drawings, designs, figures and graphics, among others, are regulated and protected. These also include cultural elements such as their music and dance.

This protection is implemented through a registry system and through promotion and commercialisation of their rights.¹⁹ The Law contains a chapter on prohibitions and sanctions. The new Penal Code of Panama of

2007 includes a section on crimes against the collective rights of indigenous communities and their traditional knowledge with punishments of four to six years in prison to those who violate these registered collective rights.

Panama has ratified the CBD through Law No. 2 dated 17 January 1995 and acceded to the FAO Treaty on 13 March 2006. Similarly, it has signed the Central American Protocol for Access to Genetic Resources (*Protocolo Centroamericano de Acceso a Recursos Genéticos* - PCARG).

Implementation status²⁰

No access permit was granted in accordance to the DE No. 257. Given the recent date of the new ABS regulations (Decree No. 25 of 2009), there are no current patent applications in the country that meet the prescribed obligation related to the submission of the certificate or origin or provenance.

Patent searches are periodically carried out in patent databases of the European Office, the USPTO and WIPO. Panamanian research patents have been found in the PCT database presented through the United States office, but these were presented before²¹ the applicability of DE 257 from 2006 or DE 25 from 2009. The search process was not considered simple, given that it requires a search strategy. The development of this strategy could be facilitated when the research reports from the granted ABS permits are obtained. According to the information received in the research reports, the potential inventions could be classified utilising International Patent Classification. The name of the molecules discovered and their possible uses could be used as key words in the searches for possible patents in foreign jurisdictions.

Aside from these activities, a better application of the certificate of origin in intellectual property applications in Panama does not exist.

4. DISCLOSURE OF ORIGIN AND FREE TRADE AGREEMENTS (FTAs)^{22 23}

With regard to FTAs, concerns have been raised that in some cases their IP provisions may limit or preclude the opportunities to introduce disclosure of origin requirements. For example, the language used in the US-Central American Free Trade Agreement (CAFTA), states that “Each party will ensure that a disclosure of a claimed invention shall be considered to be sufficiently clear and complete if it provides information that allows the invention to be made and used by a person skilled in the art, without undue experimentation, as of the filing’s date” (article 15.9.9). Doubts have been raised as to whether this text implies a restriction on additional information being requested when the patent is disclosed. The author - for legal and technical reasons - does not agree with this interpretation. However, it deserves to be mentioned as a suggested potential implication of the FTA on the disclosure requirements.

FTAs have generally not incorporated a mandatory requirement for the disclosure of origin in the substantive IPR Chapter. However, the issue has sometimes been addressed elsewhere. For instance, in the case of the US-Peru FTA, the following elements have been agreed upon in a side letter:

- i) Recognition of the importance of traditional knowledge (TK) and biodiversity, as well as their contribution to development.
- ii) Recognition of the importance of a) prior informed consent from the appropriate authority; b) equitable sharing of benefits from the use of TK and genetic resources; c) promoting quality patent examination to ensure that the conditions of patentability are satisfied.
- iii) Recognition of the fact that access and benefit sharing can be adequately addressed by contracts.

Despite the recognition of the issues in the side letter, the text agreed upon relates

essentially to uncontroversial matters (e.g. the importance of TK). In other words, the side letter does not address or respond to the more controversial aspects of disclosure of origin.

4.1 The Biodiversity Law (LB) Amendment

The Costa Rica Constitutional Court Vote (SC, No. 8-13832 from 11 September 2008) with respect to the last IP Draft Law of the “Implementation Agenda” of the Free Trade Agreement between Central America, Dominican Republic and the United States (CAFTA-DR) has confirmed the relationship that exists between the Free Trade Agreements, biodiversity (in this case regarding traditional knowledge) and intellectual property rights. In a 4-3 Vote, the majority of the court members decided that the process followed was unconstitutional for incorporating some amendments to the BL, contained in the Draft Law No. 16955.²⁴ Due to this resolution, the Executive Branch was forced to require an extension from the other members of the CAFTA-DR in order to put it in effect.²⁵

The original version of Article 78 of the BL excluded the protection of intellectual property in the following cases:

“Inventions derived primarily from associated knowledge, biological practices or in the public domain”.

The reform that was proposed in the Draft Law No. 16955 had two main objectives: 1. It establishes in the article’s header that the exclusions of protection are only applicable when related to patents and not other forms of intellectual property; 2. The following sentence was then added after “public domain”: “as long as they do not meet the patentability requirements of Law No. 6867 from June 23, 1983 (Patent Law) and its amendments.”

Although the legal reasons for these changes were not made public in detail, they seem to have been of two types: a) there are no exclusions in CAFTA for the protection of different kinds of intellectual property that could justify what was outlined in Article 78, so it was only possible to exclude the specific case of patents but not other IP; b) it was necessary to clearly establish the possibility of patenting inventions derived from the TK as long as the requirements of the patent law were met.

The draft law was consulted by a group of congressmen to the Constitutional Court, and in their response, the majority of the Judges (Magistrates) considered that:

“The central point of this claim is to establish whether the highlighted changes directly affect the indigenous communities and require consultation according to the articles of the 169 Convention of the International Labour Organisation. This Convention establishes in Article 6, the obligation of governments to:

- a) Consult with interested communities through appropriate procedures, and in particular

through their representative institutions, each time that legislative or administrative measures which are **susceptible to directly impact** them are foreseen. (...)

The reform in Article 78 in paragraph 6) of the BL, introduces an objectively verifiable change with respect to the applicable text, and establishes as patentable those which before were not, concretely, the inventions primarily derived from the knowledge associated with traditional biological or cultural practices within the public domain. With the current text, they are not patentable; with the new text, they are, if they meet the patentability requirements established in Law No. 6867 from 23 June 1983 and its amendments. *Contrario sensu*, it establishes the standard that if the traditional knowledge meets the requirements of the quoted law, then it is patentable, although it is an invention essentially derived from the knowledge **associated with traditional biological practices** or cultural practices in the public domain. Objectively, it is a change that directly affects the interests of indigenous communities, and, as a result, in conformity with the 169 Convention this amendment must be consulted...”

5. RECOMMENDATIONS

The following recommendations can be made:

- The legal texts relative to the disclosure of origin/certificate of legal origin and the consultation processes with the environmental authorities - in Costa Rica's case - should be revised so that they can better define the scope of this instrument from the technical point of view. It is necessary to regulate in detail the scope of the obligations stipulated in the legal provisions in order to facilitate its implementation and provide certainty to the different actors involved in its application. The lack of clarity and certainty could constitute an impediment in order to put this mechanism into practice.
- It is imperative to create the conditions and capacities necessary so that the environmental authorities can meet these obligations, especially through training on issues related to IPR, given that these authorities are relatively unfamiliar with the IP system. This training should include intellectual property rights authorities in order to familiarise them with the disclosure of origin or certificate instrument (including its purpose). Joint workshops - such as the one organised in Costa Rica-, could be considered. In addition, it could be useful for the IP authorities to determine in advance which is the potential and likely "universe" of IP applications which - in principle-, have used GR or TK and therefore must comply with the disclosure of origin/ certificate requirements.
- In the countries in the region that do not yet have access laws but do have initiatives in process or draft laws, the disclosure/ certificate laws should be drafted in the most homogeneous way possible. A relatively harmonised regional legal framework would facilitate training and experience exchange processes. The possible limits imposed by the CAFTA-DR and other Free Trade Agreements as well as other public policy spaces that exist should be considered in the process of drafting any disclosure requirement.
- As a component of any capacity building initiatives, the strengthening of human and technical resources of the environmental and IP authorities should be promoted in order to, among other tasks: review IP applications; identify the cases in which disclosure of origin is mandatory; carry out searches in IP databases; compile and disseminate, as appropriate, information that can be useful for destroying the novelty of patent applications presented in other countries related to GR or TK; and improve coordination with foreign IP and environmental offices.
- The exchange of experience (through internships, workshops, etc.) with countries that have established similar requirements and have developed a significant practical experience that could support the implementation of this instrument in Central America. This may include the creation of a National Anti-Biopiracy Commissions.
- Finally, it is important to follow up on the processes and international forums related to these issues and to reach a national consensus to be presented in the relevant fora and processes.

ENDNOTES

- 1 For the purposes of this document, the expression “disclosure of origin or certificate of legal provenance” refers, in general terms, to the obligation - included mainly in genetic resources access laws - to disclose the country of origin/source of genetic resources used in an invention, or to demonstrate the legality of access to the same. Depending on the specific wording of the legal provisions, this instrument may include also the evidence of the existence of prior informed consent; of the fair and equitable sharing of the benefits from said access (or an access contract); and the compliance with the legal requirements to access to genetic resource or traditional knowledge established in national laws.
- 2 Concerning technical and legal aspects of disclosure of origin, readers are referred to the following studies which, in addition to being comprehensive, present some differing conclusions on various aspects: WIPO, *Technical Study on patent disclosure requirements related to genetic resources and traditional knowledge*, Study No 3, 2005; Sarnoff, Joshua and Correa, Carlos, *Analysis of options for implementing disclosure of origin requirements in intellectual property applications*, UNCTAD, February 2006; Rojas, Martha et al., *Disclosure requirements: ensuring mutual supportiveness between the WTO TRIPs Agreement and the CBD*; IUCN, Gland and ICTSD, Geneva, 2005; Sarnoff, Joshua, *Compatibility with existing international property agreements of requirements for patent applications to disclose the origins of genetic resources and traditional knowledge and evidence of legal access and benefit sharing*, available on www.piipa.org; Ho, Cynthia, *Disclosure of Origin and Prior Informed Consent for applications of intellectual property rights based on Genetic Resources*, A Technical Study of Implementation issues, Final Report, July, 2003; and Hoare, Alison, *Background Paper for the Chatham House Workshop: “Disclosure Requirements in Patent Applications - Options and Perspectives of Users and Providers of Genetic Resources,”* 9-10 February 2006, Energy, Environment and Development Programme, Chatham House; Cabrera Medaglia, Jorge, *El Régimen Internacional de Acceso y Distribución de Beneficios: elementos, progreso y recomendaciones*, UICN, Quito, 2006. It should be pointed out that there is a lack of accurate information on the real implementation of this measure, except for the Chatam House study.
- 3 For example, Brazil, the Andean Community, Costa Rica, India among others. Cfr. Hoare, *op cit.*
- 4 Correa, Carlos, *Alcances jurídicos de las exigencias de divulgación del origen en el sistema de patentes y derechos de obtentor*, Research Documents, Initiative to Prevent Biopiracy, Year 1, No 2, August 2005.
- 5 Correa, *op cit.*
- 6 Cfr. Correa, *op cit.*
- 7 Girsberger, Martin, Transparency Measures under Patent Law Regarding Genetic Resources and Traditional Knowledge, *The Journal of World Intellectual Property*, July 2004, Vol. 7, No 4, Geneva.
- 8 However, this consultation process has been limited by an amendment to Article 80, enacted as part of the implementation package of the CAFTA-DR Free Trade Agreement.
- 9 Law No. 8686 published in *La Gaceta* November, 26 2008.
- 10 Decree No. 34958-MINAET-COMEX, an amendment to Article 80 of the BL limits the opposition on the grounds of lack of compliance with the patent requirements. Likewise,

in the case of non compliance a fine is established. The processing of the applications seems to be allowed even if no certificate of compliance was produced. A constitutional action was brought against this regulation and its pending in the Constitutional Court.

- 11 A similar case occurs with the implementing legislation of the Agreement on Commercial Promotion between Peru and the United States (Law No. 29316 published on 14 January in the Official Peruvian Diary). Law No. 29316 has amended the substantive requirement of having an access contract for genetic resources with the Peruvian State or a license contract with the indigenous communities for the use of their traditional knowledge, as a condition for being able to obtain a patent that uses GR or TK. In the case that there is no a contract, a sanction exists to penalise the applicant, but this is not a cause for annulment or invalidity of the patent. Decision 486 is modified in two fundamental moments of the IP process: the patent application and the declaration of annulment of patent that has already been granted.
- 12 The CAFTA-DR was approved on 7 October 2007 through referendum. The Law is No. 8622 published in *La Gaceta* on 21 September 2007, Reach No. 40.
- 13 The reforms introduced by Law No. 8632 to the Trademark Law and other Laws amended paragraphs c and d of article 4 of the Patent Law (exclusions to patentability), in the following way: “c) Plants and animals, except microorganisms, as long as they are not microorganisms as found in nature; d) The essentially biological processes for the production of plants or animals that are not the non-biological or microbiological processes.”
- 14 Personal communications with Karen Quesada from the Industrial Property Registry and with Maribelle Alvarez of the CONAGEBIO Technical Office.
- 15 Through the resolution from 8:07am on July 30, 2009, the application was rejected due to the lack of an invention unit, lack of clarity and because the claims are related to treatment methods which are excluded from patentability according to article 1 of Law No. 6867. This decision was appealed.
- 16 Cfr. Elia Guerra’s study, *Acceso a recursos genéticos y distribución de beneficios*, prepared for the Natural Patrimony Office of the ANAM, dated 11 March 2004.
- 17 This legislation should be amended to meet Free Trade Agreement requirements but those have not been submitted yet to the National Assembly. The Genetic Resources Unit has requested that the amendments include the obligation to disclose the origin in line with the access regulations.
- 18 The Free Trade Agreement with the United States contains the obligation of Panama to adhere to UPOV 1991 at the latest by 1 January 2010.
- 19 From 2002 to 2009, 10 registries have been granted. The protected material includes designs or textiles of molas, bags, necklaces, traditional dress, wood works, baskets, hammocks and musical instruments.
- 20 Darío Luque and Leonardo Uribe personal communications.
- 21 Cfr. Applications W0 2005/035783 A1 and W0 2004/084801 A 2. The two cases were related to the researchers from Panama and the United States and the applicant was the Smithsonian Institute.
- 22 However, there is no single interpretation regarding the consequences of this language for the possibilities of requiring disclosure of origin.

- 23 The report from the Expert Group on Traditional Knowledge Associated with Genetic Resources in the Context of the International Regimen (UNEP/CBD/WG-ABS/8/2/corr.1) mentions in its text that “an expert called the attention of other experts on the impact of the free trade agreements, such as CAFTA-DR, in imposing the obligations on CBD Members that can be inconsistent with the requirements of the disclosure of a certificate of origin” (paragraph 63).
- 24 The Draft Law amends various intellectual property laws, among them the Copyrights Law and the Patent Law, as well as the Biodiversity Law. Subsequently, the Draft Law was modified, eliminating the text of paragraph 6 of article 78 of the Biodiversity Law, maintaining its current version. The Constitutional Court determined (5-2) that this new law did not conflict with the Constitution. Finally, it was published as Law No. 8686 in *La Gaceta* on 26 November 2008.
- 25 The other countries finally accepted the granting of the mentioned extension until 1 January 2009.

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ANNEX 1. LEGAL AND INSTITUTIONAL FRAMEWORK ON ABS AND IP

Country. Belize	ABS Legal Framework	IPR regimen related to agrobiodiversity
	<p>Relevant International Conventions:</p> <ul style="list-style-type: none"> -CBD (rat. 1993). - TI (no signature). -PCABS (signed, not yet in force). <p>Relevant National Legislation:</p> <p>General legislation on research permits is found on the Wildlife Law (1981) and the National Parks Law (1981). No specific regulations exist for agriculture genetic resources.</p>	<p>Relevant International Conventions:</p> <p>Member WTO/TRIPS (1995). Not a UPOV Member.</p> <p>Relevant National Legislation:</p> <p>Patents legislation of 1862, Patents and Designs Act, Chapter No 212. Plant Variety Protection Act of 2006 (Chapter 225) based on UPOV 1978. Level of the Act's application uncertain.</p>
Costa Rica	ABS Legal Framework	IPR regimen related to agrobiodiversity
	<p>Relevant International Conventions:</p> <ul style="list-style-type: none"> -CBD (rat. 1995). -TI (rat. 2006). -PCARG (signed, not yet in force) <p>Relevant National Legislation:</p> <p>Biodiversity Law No. 7788 of 1998 and regulations for <i>ex situ</i> collections (No. 33697 of) and <i>in situ</i> access (. 31514 of 2003). A process for the development of a mechanism for the protection of TK is in place.</p>	<p>Relevant National Legislation:</p> <p>WTO/TRIPS and CAFTA-DR. Patent Law (Ley de Patentes de Invención, Dibujos y Modelos Industriales y de Utilidad No. 6867 of 1983) and its amendments excludes the patentability of plant varieties.</p>

Annex 1. *Continued*

El Salvador	ABS Legal Framework	IPR regimen related to agrobiodiversity
	<p>International Conventions</p> <ul style="list-style-type: none"> • CBD (rat. 1994) • TI (rat. 2003) • PCARG (signed, not yet in force). <p>National Legislation:</p> <p>General Environmental Law (1998) addresses ABS in a general manner. However, it mandates that any regulations must be developed for the different Ministries (sectoral approach).</p> <p>Protected Areas Law of 2005 regulates the research permits and one of its objectives is the prevention of biopiracy.</p> <p>There are administrative procedures for ABS associated to wildlife, without any specific legal support.</p> <p>In process of developing a comprehensive ABS legislation under the leadership of an NGO and in coordination with the Ministry.</p>	<p>International Conventions</p> <p>CAFTA/DR and WTO/TRIPS.</p> <p>Not UPOV Member.</p> <p>National Legislation:</p> <p>Industrial Property Law (Ley de Fomento y Protección de la Propiedad Industrial) of 1993 allows the patentability of plants (one patent was granted and several applications are pending).</p> <p>CAFTA/DR mandate that the country “make its best efforts” to ratify UPOV 91.</p> <p>A draft law has been prepared.</p>
Honduras	ABS Legal Framework	IPR regimen related to agrobiodiversity
	<p>International Conventions:</p> <p>CBD (rat. 1995)</p> <p>TI (acceded,2004)</p> <p>PCARG (signed not yet in force).</p> <p>National Legislation:</p> <p>No specific norms on ABS exist.</p> <p>A Draft Biodiversity Law has been produced, but it has not been formally presented in the Parliament.</p> <p>General provisions on research permits in the Regulation of Protected Areas (Executive Agreement No. 921-97) and in the Forestry, Protected Areas and Wildlife Law , but only in general terms.</p> <p>General Environmental Law and its regulations (No. 104/93 of June1993 and No. 109/93 of February 1994) do not make any provision on ABS.</p>	<p>International Conventions:</p> <p>CAFTA/DR and WTO/TRIPS. Implementing Law of CAFTA/DR (No. 16-2006 of 2006).</p> <p>Member of UPOV 91 (Decree No. 325-2005, published 31 January 2006)</p> <p>National Legislation:</p> <p>Industrial Property Law (No 12-99) and its amendments do not allow patents for essentially biological processes for the production of plants or animals or their varieties and plant varieties and species.</p>

Annex 1. *Continued*

Guatemala	ABS Legal Framework	IPR regimen related to agrobiodiversity
	<p>Relevant International Conventions</p> <ul style="list-style-type: none"> -CBD (rat., 1995) -TI (rat. 2006). -PCARG (signed, not yet in force). <p>Relevant National Legislation</p> <p>Provisions on ABS are found in the Constitutive Law of the National Protected Areas Council (CONAP (No 4-89) and its regulation (No. 759-90) using the research permit mechanisms.</p> <p>For the collection of plant genetic resources there is a Ministerial Agreement, and its amendments No. 177-95 (not fully implemented).</p> <p>An outline (but not the content) for a future ABS legislation was prepared, but the drafting process did not continue.</p>	<p>Relevant International Conventions</p> <p>CAFTA/DR and WTO/TRIPS</p> <p>UPOV 91 Member (Law No 19-2006)</p> <p>Relevant National Legislation</p> <p>Plant Patents are allowed, but the requirements to be met are the same from UPOV (Industrial Property Law No. 57-2000 and its amendments).</p> <p>No known cases of patents granted so far, but several applications are pending.</p>
Nicaragua	ABS Legal Framework	IPR regimen related to agrobiodiversity
	<p>Relevant International Conventions:</p> <ul style="list-style-type: none"> • CBD (rat., 1995) • TI (accessed 22 November 2002) • PCARG (signed, not yet in force). <p>Relevant National Legislation:</p> <p>General provisions of ABS in the General Environmental Law of 1995 and its regulations.</p> <p>Draft Biodiversity Law is pending in the Congress. Detailed provisions on ABS are contained in the Law.</p>	<p>Relevant International Conventions:</p> <p>WTO/TRIPS and CAFTA/DR.</p> <p>Member of UPOV 1978 since 2001.</p> <p>CAFTA-DR makes mandatory the accession to UPOV 91 no later than 1 January 2009.</p> <p>Relevant National Legislation:</p> <p>Plant Variety Legislation is a hybrid between UPOV 78 and 91. Law No. 318-99 and its regulations No. 37-2000.</p>

Annex 1. *Continued*

Panamá	ABS Legal Framework	IPR regimen related to agrobiodiversity
	<p>Relevant International Conventions:</p> <ul style="list-style-type: none"> • CBD (rat. 1995.) • TI (acceded 13 March 2006). • PCARG (signed not yet in force). <p>Relevant National Legislation</p> <p>Environmental Law (No 41) mentions ABS, and the issue is developed in detail in the Decree No. 25 del 2009.</p> <p>Resolution AG-0208- 2007 creates the ABS Unit, as part of the Office of Protected Areas and Wildlife of the Environmental National Authority (ANAM).</p> <p>Legislation (No. 20 of 2000 and its regulation No. 12 of 2001) provides for the protection of TK (with focus on folklore) in observance and in application (10 registries).</p> <p>Criminal Code amendments of 2007 create a crime against the misappropriation of protected TK</p>	<p>Relevant International Conventions:</p> <p>WTO/TRIPS.</p> <p>Member of UPOV 78 (1999).</p> <p>Relevant National Legislation</p> <p>Patent Law No 35 of 1996 excludes patents for plants.</p> <p>Law No 23 of July 1997 and its regulations (1999) protects the plant varieties in accordance to UPOV 78 provisions.</p> <p>FTA signed with the US but not ratified in that country. A mandatory provision for the ratification of UPOV 91 was established in the FTA.</p>

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