

Access To Genetic Resources, Protection of Traditional Knowledge, And Intellectual Property Rights: Lessons Learned From The Costa Rican Experience^[1]

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1. Introduction

The knowledge, innovations, and practices of indigenous peoples and local communities (LC) have importance for the welfare of our societies, medicine, crop improvement, development of sustainable agricultural practices, etc. This is also true of wild and domesticated genetic resources and the knowledge associated with them^[3]. The role of plant genetic resources for securing food supplies is acknowledged^[4]. Contributions made by the biological diversity to the invention and several authors have described production of new medicines and drugs^[5]. The same can be said about the use of traditional knowledge (TK) in the development of new assets and services, especially in the areas of medicine and agriculture.

This paper provides basic information on the Costa Rican experience regarding access to genetic resources, the distribution of benefits, and the establishment of *sui generis* systems basically derived from the adoption and implementation process of the Law of Biodiversity. The objective is to present the lessons that may be learnt from the experience of Costa Rica in this area.

II. Importance of the Debate

The biological wealth of tropical countries, the associated TK coupled with the new biotechnology techniques have led to a reconsideration of the "hidden" value of these assets. The interest of agrochemical, seed, and pharmaceutical enterprises in

Bioprospecting in our natural environments and in using associated traditional knowledge as a guide in this has rapidly increased. Access to Costa Rica's biological resources and knowledge requires compliance with the following requirements

- Securing prior informed consent (PIC) of the State and other owners of the biological, genetic, and biochemical knowledge or resources.
- Negotiation of the sharing of benefits derived from the access to the biodiversity and the associated TK, through an agreement or contract based on "mutually agreed terms" under which the access is granted.
- Conservation of the biodiversity and establishment of the competence of national entities to give aggregate value to the natural resources of the country.

The aim is to control the access to biological, genetic, and biochemical resources and to protect all knowledge, innovations, and practices of local communities and indigenous people, especially those that exist in some of the countries in the region. It is now recognized that for centuries indigenous people and peasants have developed their own systems, practices, and knowledge on agriculture disease control, natural resource management, and medicine. This knowledge is useful and of great values to social sectors others than those who created and developed it with their intellectual effort. In the past work on traditional improvement of crops and animals and associated indigenous knowledge was considered a non-exclusive public asset, which could be accessed freely and without cost. It was considered a "Common Heritage of Mankind." However, from these genetic resources, which were obtained at no cost whatsoever, diverse products were developed such as new plant varieties, pharmaceutical products, insecticides, etc., which then became private property and subject to intellectual property rights. They were then made available under the name of plant collection rights, patents of invention, and trade secrets to developing countries at a certain price.

The inequity of the genetic resources supplied without cost by the South and the processed products having to be bought at a price from enterprises from the North was justified on the basis of the concept of biological diversity being defined as a Common Heritage of Mankind, i.e., a public asset, which could be used without having to make any payment. This allowed the genetic richness of developing countries to be extracted and used without any compensation. Insecticides, medicines, and improved seeds derived from the vast genetic wealth and frequently using approaches based on TK are made available under the concept of private property and must be paid for.

Parallel to the emergence of an international conscience that rejects the Common Heritage of Mankind concept, new biotechnologies (basically DNA ^[PKV1]recombination and cellular fusion), progress made in the field of microelectronics, and other techniques used to test biological materials have revitalized the interest of pharmaceutical, chemical, seed, and biotechnological enterprises both in genetic resources that are found in the wild as well as in the associated traditional knowledge.

CBD has tried to change the way things stand. However, the benefit of this depend on each individual country and on the capacity for cooperation and coordination that exists among them for establishing policies and laws to regulate access to their biological

natural resources and TK, and for sharing of benefits thereof.

The International Convention establishes as one of its objectives fair and equitable sharing of benefits derived from access and use of biodiversity. Thus regulating the access to these resources (and associated knowledge), subjecting this access to the laws of the country, and to a fair and equitable sharing of the benefits with the different stakeholders^[6].

The implementation of articles 3 and 8 still lead to deep and complex debates and little progress has been made in resolving the underlying issues. This constitutes an important challenge for local groups, indigenous people, governments, regional entities, and in general, the international community. The way in which these provisions were implemented in Costa Rica will be analyzed below.

III. Some Reflections on the Biodiversity law in Costa Rica

The processes used to draw the **Law of Biological Diversity** (LBD) and specially those pertaining to the issues of access, protection of TK, and IPRs are particularly relevant. In 1996, when the Biodiversity Bill was restrictive and contrary to national reality and scientific research. Several comments and criticisms were made. Numerous observations were sent to the Legislative Assembly (Parliament), including a complete bill prepared by the Advisory Commission on Biodiversity, which was never formally processed legally^[7].

In January, 1997 a second version of the bill was presented, which – despite considering some of the main objections made to it - repeated several of the concepts and provisions of the former bill and, therefore, met with the same opposition. The impasse due to the opposing points of view led to the creation of a Special Mixed Commission of the Legislative Assembly in order to draft a bill based on the existing text after having obtained the promise from the Assembly to respect any agreement reached by it. The Commission was chaired by the National University and was comprised the main political parties, the Advisory Commission on Biodiversity, the Peasant Board, the indigenous Board, the Union of National Chambers, the University of Costa Rica, the National Biodiversity Institute (INBio), etc.

At the end of 1997, a new draft of the project was completed, which was sent to Congress for its approval. With some changes to the text, it was finally passed and published as a Law of the Republic in May 1998. When preparing the provisions related to the access, distribution of benefits, and protection of traditional knowledge a series of topics were considered, such as: resources covered (scope of application), basic definitions; procedures to grant prior informed consent (PIC) and mutually agreed terms; competent authorities; procedures used; terms for the distribution of benefits, penalties, etc.^[8]

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[3] see UNCTAD, 2000, RAFI, 1994 and Cabrera, 1998.

[4] Dutfield 2000

[5] See the list of products derived from the biodiversity provided by Cragg 2000.

[6] Arts. 15, 16, and 19.

[7] Cabrera, 1999.

[8] For the aspects that these systems must address, see Glowka, 1998

A. Aims of the LBD and Access Procedures

In spite of the criticisms arising from the ambiguity of some of the standards, the LBD aims to set clear regulations for access to bio-resources and TK, and sharing of benefits that may be derived from it. Before this law, only some provisions of the Wildlife Conservation Act on permits for the collection of species of plants and animals and some research regulations, especially in relation to national parks, existed. There were no modern rules to regulate agricultural matters. The new Law (LBD), whose application and interpretation is yet to be seen, establishes the bases for granting of access permits and contracts. It contains in Article 7 clear definitions of crucial topics such as the access to biochemical and genetic elements, bioprospecting, PIC, biochemical and genetic element, access permit, etc.

Access and bioprospecting definitions delimit the application of access procedures and at the same time address existing concerns on the subject. If the objective of the research is an inventory, a taxonomic description, etc., it is an activity that differs from access issues, and is regulated by Article 36 of the Wildlife Conservation Act.^[PKV2]

The Law has clarified the ownership issue of genetic and biochemical resources of the wild or domesticated biodiversity, a somewhat obscure area. Article 6 declares these resources to be in the public domain; that is to say, they belong to the State which acts as an administrator and establishes two diverse ownerships: one for the biological or organic resource and the other for the genetic and biochemical resource.

The access procedure is set out in two chapters of the LBD with much precision. The competent body that grants access in first place is the Technical Office (TO) of the recently created National Biodiversity Administration Committee (CONAGEBIO)^[9] within the Environment and Energy Department. It has maximum capacity for decentralization and for defining legal instruments. It comprises^[PKV3] the Environment Department (which presides), the Foreign Trade Department, the Health Department, the Department of Agriculture, the Costa Rican Fish and Aquaculture Institute, the National Rector Committee; the indigenous Board, the Peasant Board, the Union of National Chambers, the Costa Rican Federation for Environment Conservation, and the Directorate of the

CONAGEBIO is entrusted with the responsibility of preparing access and benefit sharing policies and can revoke the rulings of the TO on access issues^[11]. The main duty of the TO is to process, reject, and audit applications to access biodiversity resources (Art. 17, sub section a); coordinate with the Conservation Areas, the private sector, indigenous peoples, and peasant communities actions that relate to access (Art. 17, sub section B). It is entrusted with the responsibility of organizing and updating a register for access applications to the components of biodiversity, *ex situ* collections, and of the "natural" and "juridical" persons who work on genetic manipulations (subsection C). The Technical Office is expected to collect and update regulations related to the fulfillment of treaties and guidelines on biodiversity issues (subsection D).

Chapter V defines the requirements and procedures to access genetic and biochemical components and the protection of the associated knowledge. CONAGEBIO is the entity responsible for proposing access policies related to genetic and biochemical elements of both the *ex situ* and *in situ* elements of biodiversity. It is expected to act as the mandatory consultative body for all application procedures for the protection of intellectual biodiversity rights (Art. 62). The Law regulates the basic requirements for access, which include Prior Informed Consent (PIC), the sharing of benefits, the protection of the associated knowledge, and the way in which the activities will contribute to conservation (Art 63). The procedures to be followed (Art. 64), the right to cultural objections (Art. 66), the Registry of Access Rights, and the protection of confidential information (Art. 67) are established.

LBD regulates with more precision the issues of granting research and bioprospection permits (Art. 69), their terms, and other limitations and characteristics (Arts. 70 and 71); the requirements to apply for access (Art. 72), the authorization of treaties signed between individuals who contemplate access to genetic and biochemical components by the Technical Office (Art. 74), and the possibility of treaties with universities and other duly registered centres (Art. 74). It stipulates that 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 transaction expenses (Art. 76).

Chapter III regulates the limits of property rights (Art. 78) and the congruency of said rights with the objectives of conservation of the biodiversity (Art. 79). The Technical Office must always be consulted in processes where IPRs are granted for components of biodiversity; and its decision in these matters is binding (Art. 80).

Lastly, LBD establishes the grounds for the protection of the traditional, indigenous and community knowledge (TK) and for the establishment of a participatory process for the determination and registration of these *sui generis* intellectual community rights (Arts. 82 and those following it). A system of fines for illegal access is established and there is a section on the framework for sanctions (Art. 112).

The new Costa Rican legislation is ahead of regulatory mechanisms of other Central American nations. In spite of some ambiguity and complexities and the lack of application, it serves as a guideline for the way in which access must be regulated.

B. Some Relevant Issues

Some relevant issues, like the need (a) to distinguish between access for agricultural purposes from access for pharmaceutical purposes; (b) of distinguishing between research for commercial purposes from research for academic purposes, (c) for quick and special mechanisms for *ex-situ* collections, etc. have been hardly considered. These are some of the deficiencies of the present legislation, which need to be removed as much as possible with appropriate regulations.

Currently there exists a draft on the Access Standards and Sharing of Benefits, which gives provisions on these matters with respect to ^[PKV4] agricultural genetic resources (including those conserved *ex-situ*). Although there are no regulations, the differentiation and procedures that are particular for this issue are topics that must be addressed in order not to unnecessarily hinder a healthy flow of resources. In theory, access regulations must regulate the sending of materials by the *ex-situ* conservation centers, which must begin with more flexible mechanisms, such as Material Transfer Agreements, duly approved by the TO.

For the protection of the TK ^[PKV5], several aspects were taken into account. The problems related to the use of existing mechanisms for the protection of this knowledge, innovations, and practices have been documented in literature ^[12]. While it is true that some initiatives for the use of traditional mechanisms related to intellectual ownership have been outlined, such as geographical indications and designation of origins, collective trademarks (see Downes and Laird, 1999), copyrights and related aspects, trade secrets, patents of invention, collection rights^[13], etc. there are problems with respect to the need for developing *sui generis* approaches for protection. Countries like Peru, Thailand, Venezuela, Panama, and Costa Rica have already presented several concrete proposals. The Third World Network^[14] has prepared one of the pioneering proposals for this.

Models have been suggested to protect plant varieties in light of the obligation of Article 27.3.B of the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Rights (TRIPS), which develops the concept of *sui generis* protection^[15]. Emphasis has been laid on how these *sui generis* systems (compatible with the mandate of 27.3.B, although evidently limited in this case to the characteristics of the same) may be used to protect this knowledge within the WTO framework. Others have mentioned the relationship that exists between intellectual property and benefit sharing, TK and conservation, and sustainable use of biodiversity. These issues were taken into account

when the Costa Rican Law was being developed.

Emphasis has been given to the manner in which these *sui generis* systems (compatible with the mandate of 27.3.B, although evidently limited in this case to the characteristics of the same) may be used to protect this knowledge within the WTO framework^[16].

Issues relating to the effects and relationship that exists between intellectual property with benefit sharing, TK conservation, and sustainable use of biodiversity were considered when the Law was being developed.

The Costa Rican system for the protection of traditional knowledge is based on the following premises:

- a) The legal access provisions ensure prior informed consent and the sharing of benefits related to traditional knowledge. The Technical Office, and eventually the National Biodiversity Commission itself, has the authority to control, authorize, and review (Art 63, 65, 66, 72, among others) this issue.
- b) Prior Consent and sharing of benefits is a combination between access mechanisms, contracts or licenses and a *sui generis* approach based on registers.
- c) The existence and validity of various forms of knowledge and innovation and the need to protect them using appropriate mechanisms (Art. 77), be they patents, trade secrets, copyrights, plant improvement rights, *sui generis* community intellectual rights, etc. have been recognized (Art. 78).

The legislation is oriented towards the protection of knowledge by means of a registry system. ^[17] The collective knowledge of indigenous Peoples and Access to Genetic Resources, among others needs to be acknowledged. Thus an inventory will be made of *sui generis* intellectual community rights that the community's request be protected (Art. 84). However, these registry systems have been criticized for the difficulties that they can cause (see Ruiz 1999, and Downes and Laird 1999b). The following are the main criticisms against these systems: (i) the need to define "access to information"; (ii) the control exercised over said information; (iii) the possibility that communities that are not involved in the access grant prior consent to use the knowledge registered under the name of others; (iv) limitations of the restriction to the access to information

To define the scope, nature, and requirements of these rights a participative consultative process must be started with the indigenous and peasant communities (Art. 83 of the Law of Biodiversity). This process will determine the manner in which intellectual rights of the community will be used, who will hold the title and identify the ones to receive the benefits (Art. 85).

^[9] Initials in Spanish

^[10] Article 15, LBD

^[11] Article 14, LBD.

^[12] See Dutfield 2000, Posey and Dutfield 1996, Axt et al. al. 1993, Cabrera, 1998, among others.

^[13] See the analysis of this applicability in WIPO, 2000

^[14] Singh Nijhar

^[15] See Leskien and Flitner, 1997

^[16] We must clarify that the concept of *sui generis* systems included in the TRIPS is much more limited and is conditioned by the characteristics of this Agreement and thus is different from the notion of a *sui generis* system in the sense of particular, of its own class, etc., which can be developed to protect the TK, independently from the references in Art. 27.

^[17] In practical terms this has been set into motion in India (see Kaushik, 2000, Dutfield, 2000), Venezuela (Márquez, Pers. Com.) and in the Peruvian draft proposal Regime for the Protection of the Collective knowledge.

C. Specific Issues for Consideration

To assign rights and obligations, whether private or collective, the following specific issues need to be considered:

- Materials to be protected;
- Protection procedures;
- Granted rights and against whom these will be enforced;
- Enforcing mechanisms

In the case of Costa Rica some of these issues have been addressed while others are yet to be defined through a consultative process. Salient points relating to these issues are as follows:

- **Materials to be protected:** The materials to be protected are knowledge, innovations, and practices of local communities and indigenous peoples. There are others that have not yet been defined these comprise those that are associated to genetic and biochemical resources (Art. 82); and includes those used in medicine, agriculture, etc., but excludes folklore expressions^[18].

The possibility of regulation by sectors (medicine, etc.) carried out in a progressive manner must be analyzed (for example, some proposals have focused on regulations for traditional medicine, leaving other topics for later discussion). However, some issues are yet to be defined, such as the requirements to determine what is to be

protected and the powers of the entity in charge of the Registry (in this case, the Technical Office of the Commission, Art. 84.). Otherwise, there is a risk of taking more from the public domain than what is justified, creating speculative demands, and generally speaking, preventing the awareness of the scope of the rights and obligations of third parties and the actions that infringe the agreed rights. For example, in the Peruvian case cited, if the knowledge is found in the public domain it is possible to omit the prior consent, although its use does grant the right to compensation by means of the Fund created by the proposal, maintained by the payments arising from the use of protected resources (0.5% of the sales derived from its marketing). Evidently, some characteristics of these rights, for example, their evolution and adaptability, must be recognized in order to take the precautions needed in the registry system.

- **Registry procedures:** In the Costa Rican case it is voluntary and declaratory, free of charge, unofficial, informal, and for an indefinite term. Other elements like the possibility of opposition, the existence of an advisor who knows the grounds for repeals and annulments; appeals, etc., must be indicated in the procedures. The relationship between this protection and others that can be claimed through the traditional IPR scenario must likewise be acknowledged (for example, geographical indications, brands, etc.).
- **Granted rights:** Costa Rican Law has little to say on this issue, but the rights can be extracted from several provisions e.g. [\[PKV6\]](#) the need for the PIC and for mutually agreed terms for the benefits in cases of access and use; the right to cultural objection to oppose its use due to religious reasons, etc. In general, the rights derived from the existence of *sui generis* intellectual community rights must be defined. This is an issue as critical as the scope (limitations) of the said rights. And, of course, its limitations must be defined, in terms of loss? mandatory permits, etc. The fact that they are community rights does not exempt them from the above-mentioned modes. Another issue to be regulated has to do with the collective character as opposed to the private character of said rights. The Law mentions their community nature, which doesn't necessarily mean that they cannot be private. In this sense, especially in local communities, the assumption that all knowledge is generated in a collective manner is difficult to uphold.
- **Observance of the rights:** If no substantial mechanisms are established for enforcement of the rights protective regulations will not suffice. In Costa Rican Law this issue is only addressed through a fine for illegal access through the requirement to present the certificate of origin and the approval of IPRs. The mandatory consultation with the Technical Office of CONAGEBIO regarding IPR [\[PKV7\]](#) applications that use resources or knowledge and the binding nature of the decisions of Technical Office underpin this requirement [\[19\]](#).

Finally, the success of the regulations will depend, to a large extent, on the existence of the aforementioned mechanisms and the participative consultation process regarding the scope of the regulations. For this, the experience of India, the Peruvian bill, and the documentation and database registries that are being prepared in Venezuela, among others, can be used.

In addition reference must be made to the recommendations issued by the Panel of Experts on the access and sharing of benefits of the CBD, related to *sui generis* systems, according to which, as components of a possible *sui generis* law the following must be taken into consideration:

- Acknowledgement of ancestral rights with respect to knowledge, innovations, and practices related to genetic resources.
- Acknowledgement of the same even in cases where the information could be in the public domain.
- Establishment of the principle that ancestral rights related to TK can have a collective nature.
- Distinction between rights over genetic resources and rights over knowledge.
- Supposition that the use of genetic resources also implies the use of the associated knowledge (TK).
- Establishment of administrative and legal procedures to remove controversies.
- Creation of obligatory mechanisms for equitable benefit sharing among the custodians, be they a party or not to the access agreements.
- Establishment of local registers.
- Development of programs and processes to strengthen traditional knowledge systems.

Likewise, the recent fifth *Conference of the Parties of the CBD* specially considered the need to promulgate *sui generis* protection systems (Decision V/16 of COP V).

IV. Creation of Access Regimes; Difficulties and Protection of Traditional Knowledge; Obstacles and Opportunities according to

The Costa Rican experience

Diverse analysis of cases related to ABS and protection of TK has been reported in literature [\[20\]](#).

The Costa Rican experience describes obstacles and achievements related to the regulation of access to genetic resources, intellectual property, and TK. There are two points of view, in some sense contradictory, regarding the regulation of the access to genetic resources (Callaux, Ruiz, and Tobin, 1999):

- § Treating the protection of the TK and access only as a *strategy* to conserve genetic resources and associated practices, or else, as a way to prevent their improper use and appropriation, especially through a system of intellectual property rights. Accordingly it would be enough to keep registers that conserve and safeguard the information, publications, and other mechanisms that will prevent their inappropriate misuse (destruction of the novelty of patents, law of undisclosed information, etc.).
- § Treating access to genetic resources as a *mechanism* that, while granting this protection, also plays an important role in the sharing of benefits and compensation for the commercial use of knowledge and resources. Accordingly it seeks instead to create or provide mechanisms for the sharing of benefits.

This paper supports the second viewpoint given above.

Main lessons from the Costa Rica experiences on the key issues of access, protection of the TK, and IPRs may be summarized as follows:

A. Bioprospection issues

Bioprospection entails explorations of biodiversity for useful biological resources. The bioprospector, despite the diverse studies that show the potential benefits that exist on the subject, does not know for sure what he will find in the rich tropical forests, etc. Richness in biodiversity terms does not necessarily translate into commercial products such as new medicines, seeds, etc. While it is true that this risk can be offset with keys like traditional knowledge, which significantly increase the possibilities of success^[21] the uncertainty of the final destination of the research still remains, and in this issue it is important. For example, the Cancer Institute has collected and processed thousands of samples since the mid 80s, of which few have reached pre-clinical or clinical phases^[22]. Likewise, there is no product in the market that was a great success in terms of royalties.

In this sense, those who have asserted that bioprospection would become a "green gold mine" have had to modify or moderate their observations. Let's take, for example, the Costa Rica the income obtained from bioprospection is a mere than 5 million US dollars in cash, in addition to other ^[pkv8]significant contributions (in technology, training, equipment, contribution to the System of Conservation Areas, and, what is more significant, the creation of national and negotiation capacities). Although this last aspect is the most outstanding and significant in respect to acquired benefits, it must be recognized that if we consider that eco-tourism contributed in only one year some 500 million US dollars, the rate of return from bioprospection is relatively small when considering the amount of money obtained. From this perspective, bioprospection is a component of a more extensive strategy for the conservation and sustainable use of the biodiversity, rather than the solution to immediate conservation needs.

Simpson et al (1995) consider that genetic prospection may turn out to be of no great help in the war to preserve biodiversity-rich habitats, considering it unlikely that the income received from pharmaceutical research will generate significant funds. In his opinion, this conclusion is relevant whether or not the signing of a single contract or the vertical integration approach in investigations is adopted. Consequently, they conclude that the importance of contracts and vertical integration as a conservation strategy is being overrated.

On the other hand, the cost of introducing medicine to a market of approximately 230 million dollars (Gámez and Sittenfeld, 1993) versus the value of individual samples has led to the assertion that a greater compensation for bioprospection projects is difficult to justify provided the capacity of the countries, communities, and institutions does not allow the granting of an added value to samples or extracts^[23]. Otherwise, the status of our nations and communities will not stop being that of mere providers of raw materials for high-value industries which process them outside of our borders.

^[18] This is contrary to the recent Panamanian Law "Of the Special Intellectual Property Regime on Collective Rights of the Indigenous Population" No. 26 of June 2000, which only regulates this issue.

^[19] The Panamanian and the Venezuelan Law (*Law of Biodiversity*, No 5468, May 2000) contemplate greater provisions for civil and penalty sanctions, and for administrative measures.

^[20] refer Carrizosa 2000, CBD documents on benefit sharing cases presented to the *IV Conference of the Parties*, among others.

^[21] (Balick cited by Cabrera 1998 mentions an increase of 400 percent).

^[22] (Reid, 1997)

^[23] (Asebey et al, 1995).

B. Role of the State and Procedures

It is probable that the existence of historical inequities regarding ABS has led us to consider the need of strict controls that prevent the so-called "biopiracy." The regulations of some countries like the Philippines have shown how this type of approach results in non-realization of the objectives of the CBD and national laws, in spite of the good intentions of the proponents of such measures. In this sense, some of the regulations issued to date have focused more in controlling instead of promoting access.

These types of laws are generating high transaction costs and bureaucratic procedures, and they definitely bring in their wake absence of applications for access, without which it is impossible to talk about benefit sharing. The issue of transaction costs and draconian regulations that prohibit application has been specially considered by the Panel of Experts of the CBD and the Conference of the Parties (COP), recommending ways in which to lower these costs and procedures that result in access limitations, for example, by adopting measures in user countries^[24]. As long as the idea persists that access represents a way of colonialism instead of a mechanism for the generation of appropriate joint initiatives for all participating parties, the possibilities of generating desirable results will be much more limited. The revision of Philippine regulations is a good example.

In other words, the likelihood of sudden imposition of draconian access systems, both at a national (even local) level as well as at a regional level, has created significant uncertainty among the users of such resources. Efforts that have sought absolute access control have demonstrated have discouraged the initiatives to reach access agreements.

Moreover, the lack of legal certainty has increased regarding the way in which Prior Informed Consent can be secured and the required permits granted and contacts signed. In addition to legal guarantees it is necessary to have regimes that are adequately flexible and transparent. Likewise, a balance between confidentiality and transparency and availability of the results of the negotiations must be reached. However, this flexibility may be more easily obtained if the governments of the countries where the users reside take measures to guarantee the sharing of benefits. To date, such responsibility has fallen on the provider countries and it is becoming evident that this needs to change.

An example of the above is found in the words of the former Minister of the Environment in Colombia, who manifests that one of the motives for the negotiation of the Andean Decision 391 on the Access to Genetic Resources consisted of "... *the economic potential of biodiversity, as a source that could contribute to our development. At that moment we foresaw a great demand for access to the genetic resources of the countries in the area and, consequently, thought of the need to have tools to maximize our opportunities and protect our rights. It appears that recent history did not prove us right on the number of interested parties who would come on their own initiative to knock on the doors of the governments...*" ^[25]. It is clear that without access there is no benefit from genetic resources.

C. Linking Access with National Strategies for the Conservation and sustainable use of Biodiversity

The evolution of legal systems to secure access genetic resources has taken place separately from the development of national policies on conservation and sustainable use of biological diversity. It should be noted that benefits, both monetary and non-monetary, contribute in a tangential manner to the conservation process. Practical negotiations to allow access can help in realizing much wider objectives if nations, through highly participatory mechanisms, establish public policies on this issue. In any case, these national policies must serve to develop and strengthen national capacities and institutions, which will lead to an increase in the value of these resources.

D. Unique Character of Genetic Resources for Food and Agriculture.

Genetic resources have unique contributions to make to food and agriculture. The former for several reasons, such as their interdependency, their relevance for food safety, their ex-situ supply of the same.^[26] Consequently, discussions within the convention as well as future national regulations must take into consideration the special nature of these resources and thus foresee special access systems (including the so-called simplified access), as well as be congruent with a multilateral access system, like the one negotiated under the sponsorship of the United Nations Food and Agricultural Organization within the framework of the revision of the "International undertaking on Plant Genetic Resource" ("*Compromiso Internacional sobre Recursos Fitogenéticos*"). The parties should not establish legal measures that prevent the flow of these resources and hinder the operation of a multilateral system, with the condition that they contemplate an appropriate sharing of benefits, in terms of financial resources, transfer of technology, training, etc.

Taking this reasoning further the existence of collaboration mechanisms and networks in agricultural matters must also be recognized. Their operation has provided significant benefits to farmers and, consequently their modus operandi, with some modifications must be supported^[27].

E. Definition of Property Rights

It is crucial that property rights over genetic and biochemical resources are defined. The Convention only mentions the sovereignty of the States over them, without taking into consideration existing property rights. It is important to clearly distinguish among the concepts of property, sovereignty, and national heritage (see Ponce, 1996) to design a mechanism for ensuring legal certainty. The absence or uncertainty regarding the ownership of genetic resources implies difficulties in securing PIC and in general for determining participation in access negotiations. This in turn makes it difficult to draw appropriate access agreements due to the doubts that exist and the company requirements to have appropriate guarantees regarding the legality of the procedures for avoiding public and legal problems.

F. Strengthening the participation of local communities and Indigenous people

To a great extent, the success of access regimes in contributing to the conservation of biological wealth depends on the extent to which the custodians of this wealth participate appropriately in the sharing of benefits and, consequently in the definition of the legal and political frameworks related to the access. Only to the extent that these people who are also holders of important knowledge and innovations, get involved and are heard and taken into account, can access to genetic resources become a useful mechanism to safeguard biodiversity. In this sense, considerations of ethical nature are of utmost importance and access is not simply a commercial initiative, detached from the deep ethical implications of the use of certain resources and knowledge.

G. Access and Technological Change

In accordance to Reid (1997), we can assert that technology plays an important role, albeit in a certain sense contradictory, in access issues. On one hand, new research techniques, recombining biotechnology, etc., have opened the doors to the use of the components of biodiversity in an unknown way and has increased the value of these resources and knowledge as a whole. On the other lesser operational costs and the need to work with smaller amounts of samples have caused the tangible value of such resources to decrease. .

It has become necessary be alert to the changes in technology for eventually, advances in combinatorial chemistry, etc., may lessen the interest in the biodiversity, access to bio-resources, and use of TK.

H. Access and its Impact on Basic National Research

Access regulations are based on the idea of conserving biological diversity, its sustainable use, and the fair and equitable sharing of benefits. Basic research is an indispensable component in order to be able to reach these goals, specially when missing crucial information on ecosystems, species, etc. In view of this research conducted by universities, centers, etc., constitutes on its own an element that contributes to this process. Access rules may be negatively interfering with it and they definitely affect the reaching of the objectives of the Convention, due to the idea of controlling non-scientific activities in order to regulate the resulting commercial benefits. This undesired impact must be avoided through appropriate procedures that favor basic research activities.

V. Relationship between Access and Intellectual property Rights: Some Questions

During the writing phase of the LBD, and as a part of the preparation of access and benefit sharing regulations, the unavoidable issue of intellectual property rights, and their relationship with the same, arose. Article 16 of the CBD recognizes that these rights must support and not oppose the objectives of the Convention. Diverse stands have been taken in relation to this issue, some of which assert the complete incompatibility between the CBD and the recent developments of intellectual property rights (see GRAIN and GAIA, 1999)

Thus, the LBD establishes the need for IPRs to be congruent with the objectives of the Law in virtue of the integration principle (Art. 79). The Law excludes from being patented: DNA[PKV9] sequences per se; plants and animals; unmodified microorganisms;

essentially biological procedures for the production of plants and animals; natural cycles or processes themselves; inventions essentially derived from associated knowledge or traditional biological practices or of public domain; inventions that, when monopolistically exploited may affect agricultural products or processes considered basic for food and health (Art. 78).

Some have asserted the contradiction of several clauses in the TRIPS [\[PKV10\]](#) Agreement [\[28\]](#) and, therefore, according to the Costa Rican scenario, with the Constitution itself, as in our legislation treaties have a higher value than the ordinary Law and cannot be disregarded by it.

At the same time, some important doubts must be highlighted [\[29\]](#) which expressly or implicitly was the cause of these regulations:

- Are traditional IPR systems always inadequate to protect knowledge, innovations, and practices as asserted by most supporters of the doctrine or, on the contrary, can be used to protect important sectors of the same, for example, by the use of trademarks, certificate of origin, etc.?
- What are the possibilities that the IPR establish value for the biodiversity and associated knowledge – in an indirect manner – when protecting a market of products that use genetic resources? If in this case the answer is affirmative, to what extent can these mechanisms be used to claim this value? (See Lesser, 1998).
- Is it possible and feasible to establish the Certificate of origin (refer Tobin, 1997), in a way that it is required to present a certificate or document to show that the benefit sharing and access are legal before granting intellectual property rights for products or processes that have used genetic resources and TK? This instrument has been contemplated in the Peruvian regulation on plant collecting (Decree No. 008-96-ITINCI), Decision 391 of the Andean Community on the Common Regime over Access to Genetic Resources, in Decision 486 of the same regional entity on an Industrial Property Regime, in the LBD of Costa Rica (Art. 80), the temporary measure on access to genetic resources and sharing of benefits of Brazil (No. 2052), among others. This issue has been discussed in the WTO, basically in the TRIPS Council and in the Committee of Trade and Environment, in which different countries and groups have presented proposals to include the same in the review of TRIPS. Likewise, other fora like the Patent Treaty of the WIPO and the Biotechnology Working Group have addressed the issue, and possibly the recently created Intergovernmental Committee on Traditional Knowledge, Genetic Resources, and Folklore will study it and make recommendations. At the same time, it must be considered that diverse objections have been made against the same, ranging from its incompatibility with patent tax requirements of the WTO (Art. 27 of the TRIPS) to criticisms of a practical nature [\[30\]](#).
- To what degree do the IPRs have an impact on biodiversity, for example through restrictions on the exchange of seed through patents, collection rights, contracts, or technology for the control of gene expression? To what extent can there be impediments in traditional practices due to patents or other rights granted to inventions that claim the use of genetic resources, even if from a legal point of view, they should have never been granted as they were not new or they lack the level of invention (as has been discussed in respect to Neem, Turmeric, or the *Ayahuasca* plant, many of which have been revoked in the United States or Europe)? Can they restrict the export of traditional products (beans in Mexico [\[31\]](#), etc) through the discussion over the existence of collection rights or patents granted in the import market to third parties, based on the characteristics of these products?
- To what extent do the IPRs have a direct impact on the environment and conservation and sustainable use of genetic resources and traditional knowledge? For example, to what extent do they aid or impede the transfer of healthy environmental technologies; avoid or reduce the negative effects such as genetic erosion; increase the use of synthetic chemicals (specially dealing with the sale of transgenic seeds that are resistant to weedicides); direct investigations and development towards undesired areas and create homogeneous agriculture that is little adapted to local needs, etc.?
- Can the *sui generis* system be used for plant varieties foreseen by the WTO in its article 27.3.b to protect traditional knowledge, stipulate the sharing of benefits, etc., in spite of the fact that in the framework of the TRIPS this expression acquires a unique meaning (see Leskien and Flitner 1997)?
- Does it enable the stipulation of IPRs in access contracts, guarantee greater returns to the countries of origin or local contractors, including communities and populations, provided this protection entails greater income for the enterprises involved in the absence of copies and competition? Do they then constitute a mechanism that in the case of commercialization makes provisions for higher

[24] (Panel of Experts, 2000).

[25] cited by Carrizosa, 2000

[26] See Dutfield 2000 and Astudillo, Salazar and Cabrera, 2000

[27] See Sain, Cabrera, and Quemé, 1999.

[28] See Carvalho 2000

[29] See Cabrera and Alaracón and Cabrera, 2000

[30] Difficulty regarding plant varieties whose origin comes from different countries and crossbreeding and retrobreeding; the fact that a patented process or product does not always necessarily reach the market; the additional workload for the Office of Industrial Property; the lack of patenting of multiple products derived from the tropical biota, etc.

[31] In December of 1999, the company POD-NERS of the United States started a legal action with the import of beans from Mexico, arguing that the same contravened intellectual property rights on bean varieties, which apparently descend from varieties widely eaten by Mexicans. In fact, the origin of the acquisition of genetic material dates back to the purchase made by the President of said company of a bag of commercial seeds in Sonora. The plaintiff requests royalties of around 6 cents of a dollar per pound of beans. For further details, see RAFI, 2000.

VI. Lessons learned in the Negotiation of Access Contracts and its Potential Applicability for the Protection of TK

This section contains the main lessons learned from the negotiation process relating to agreements and contracts by the National Institute of Biodiversity, a private, non-profit institution. The structure, policies, and programs of INBio have been discussed in several publications (see Gámez et al, 1993). In general, significant experiences have been gained regarding the sharing of benefits since the Agreement was signed with Merck & CO in 1991. At the same time, INBio signed an Agreement of Cooperation with the Ministry of the Environment, by which it commits itself to granting it 10 percent of the research operation budget and 50 percent of the royalties that it will eventually get, besides other benefits related to training, etc.

To date, a series of collaboration agreements have been signed [32] such as:

- a. Academic agreements with Universities and other research centers (University of Costa Rica, National University, Strathclyde, Massachusetts, etc). Although different, all of them are oriented toward the search of knowledge and new products through research and collaborative approaches.
- b. The Cooperative Biodiversity Group, together with Bristol Myers, Cornell University, and the University of Costa Rica, whose intention was to obtain useful substances from insects and increase human resources and knowledge of ecology, taxonomy, and chemistry?
- c. Agreement with INDENA, an Italian pharmaceutical company, for the search of antiviral and antimicrobial activity of natural components.
- d. Agreement with Givaudan-Roure Fragrances, whose objective was to identify and collect fragrances and aromas from the ecosystems in order to commercialize new perfumes, extracts, etc.
- e. Agreement with La Pacífica and British Technology Group, for the domestication, extraction, and evaluation of a potential nematicidal effect of the DMDP plant, which could represent significant benefits with the substitution of synthesis chemicals.
- f. Agreement with Diversa for the prospection of enzymes with industrial potential derived from microorganisms.
- g. Agreement with Phytera to obtain crops *in vitro* from diverse plant species for purposes of identifying in them metabolites that can be useful to the pharmaceutical industry.
- h. Agreement with the Strathclyde Institute for Drug Research, for purposes of finding new pharmaceutical products and the effective distribution of the extracts prepared by the Program to a greater amount of enterprises related to bioprospection.
- i. Agreement with Eli Lilly for purposes of finding pharmaceutical and agricultural uses for plants.
- j. Agreement with AKKadix Corporation for the isolation of bacteria from soil samples and Costa Rican plants, etc.

These and other contract relationships have provided great benefits of the following type:

- Monetary benefits through direct payments.

- Payment for supplied samples.
- Covering research budgets.
- Transfer of important technology which has enabled the development of the infrastructure at the Institute (biotechnology lab, etc.), which can be used for the investigation and generation of their own products.
- Training of the scientists and experts in state-of-the-art technology.
- Negotiation experience and knowledge of the market and the probabilities of searching for intellectual uses for biodiversity resources.
- Supporting of conservation through payments made to the Ministry of the Environment for the strengthening of the National System of Conservation Areas.
- Transfer of equipment to other institutions, such as to the University of Costa Rica.
- Future royalties and milestone payments to be shared 50:50 with the Ministry of the Environment.
- Establishment of national capabilities for assessing value of biodiversity resources.

The significance of the contract approach must not be underestimated. Even in knowledge registry systems, provided more than its protection and the prevention of undue appropriation by third parties is sought, the commercial use of said knowledge implies some type of negotiation to obtain a license for sales and transfers. There is thus an element of contractual agreement involved. In fact, studies carried out to date on benefit sharing for the use of the knowledge, the different joint initiatives such as the Cooperative Biodiversity Groups, etc, all are based on contractual arrangements.

The most important inferences that can be summarized from the above are as follows:

A. There must be a clear institutional policy for the criteria demanded in prospecting contract negotiations. In INBio's case, they are transfer of technology, royalties, limited quantity and time access, limited exclusiveness, not causing a negative impact on the biodiversity, and direct payment for conservation. For INBio this policy has led to the stipulation of minimum requirements for initiating negotiations, and these requirements have resulted in the rejection of some requests; for example, very low royalties; lack of will to grant training, etc. The institutional policy provides greater transparency and certainty for future negotiations. These same policies must be taken into consideration when the local communities and indigenous peoples, such as the Kuna's in Panama, adopt legal outlines (Cabrera, 1998) in the contractual arrangements entered into by them, and should include other relevant ideas such as those related to the impossibility of patenting certain elements, licensing instead of a complete transfer etc.

B. Existence of a national scientific capabilities, and consequently, the possibilities of adding value to biodiversity elements, increase the negotiating strengths and benefit sharing which are to be stipulated in contract agreements. As we previously mentioned, the need to grant an aggregated value to material, extracts, etc., is crucial if one wishes to be more than just a simple genetic resource provider. In this sense, the development of important human, technical and infrastructure capacities, through laboratories, equipment, etc., together with the institution's prestige, have permitted better negotiation conditions.

The existence of TK that can be involved in operations - which has not happened in the specific case of INBio- implies a greater scientific capacity and, consequently leads to better compensation conditions.

C. Knowledge of operational norms as well as of changes and transformations taking place in the biotechnology sector, and of the scientific and technological progresses that underlie these transformations helps in defining ABS mechanisms. It is essential to possess knowledge of how different markets operate and of the access and the benefit sharing practices that already exist in these markets. Since they vary from sector to sector for example the economic dynamics of the markets in the nutraceuticals, ornamental plants, crop protection, cosmetics, pharmaceuticals are complex and different [33]. This knowledge is needed to correctly negotiate royalties and other payment terms. How can we otherwise know if a percentage is low or high? It is crucial to be informed on the operational aspects of these markets. For example, when INBio began negotiating new compensation forms, such as advance payments or payments on reaching predefined milestones (example with Eli Lilly and Akkaddix), it was of vital importance to know the approximate amounts the industry was likely to pay in order to negotiate appropriately. Otherwise, one can be requesting terms, which are either completely off the market, or accepting some which are not adequate.

D. Internal capacity for negotiations, which includes adequate legal and counseling skills relating to the main commercial and environmental law aspects. Possibly, one of the key facts understood by the Institute is to know that negotiations involve a scientific aspect (of crucial importance to define key areas of interest such as a product, etc.), a commercial aspect, a negotiation aspect, and the respective legal aspects. These latter comprise not only the national trade law, but also the international environment law, conflict resolution, and intellectual property. For these reasons, the creation of interdisciplinary teams is crucial (Sittenfeld and Lovejoy, 1998). At the same time the

need for such a team is one of the most important criticisms to the contractual mechanisms. Solutions such as facilitators or others that pretend to "level the negotiation power" have been proposed. (Chaytor et al, 2000). Unfortunately, when one speaks of benefit sharing, and as long as no appropriate multilateral mechanisms exist, the contractual systems are inevitable. The absence of this interdisciplinary team is equivalent to keeping one of the parties at a disadvantage particularly if we consider that pharmaceutical companies possess enormous legal and negotiation capabilities.

E. Innovation and creativity capabilities for obtaining compensations. An ample spectrum of potential benefits exists. In the past, interesting benefit sharing formulas, other than the traditional ones, were developed through the appropriate use of negotiations, and include for example fees for visiting gene banks having collected material, etc. The contractual path fortunately permits parties to adapt themselves to the situation in each concrete case, and from there proceed to stipulate new clauses and dispositions.

F. Understanding in key subjects such as: rights on intellectual property; importance of warranties on legality; clauses on ways to estimate benefits (net, gross, etc.); requirements and restrictions on third party transference of the material (including subsidiaries, etc.), and the obligations of such parties; precision of the key definitions provided they condition and outline other important obligations (products, extracts, material, chemical entity, etc.); precision of the property and ownership (IPR and others) of the research results, and joint relationships, etc.; confidentiality clauses in the agreements and how to balance the same in relation to the need for transparency in the terms of the agreement; termination of the obligations and the definition of the survivor of some obligations and rights (e.g. royalty, confidentiality, etc); conflict resolutions.

In the negotiated agreements, the complexity of the same has been made clear, and this is related to sub-clause D. For example, what outcomes give rise to benefit sharing, such as royalties, will depend on the nature of the definitions, such as product, extract, entity, etc. A more comprehensive definition gives rise to a better position. Likewise, delimiting the areas or sectors where the samples can be used, the net sales, and what is possible to exclude from them, are only examples of some aspects that must be specified, etc. Likewise, the procedures and rights in the case of joint and individual inventions are of interest (preference and acquisition rights, etc.), as well as the conditions for the transfer of material to third parties (under the same terms as the main agreement, need of consent or information, transference to third parties so that certain services can be performed, etc.).

G. Proactive focus according to institutional policies. There is no need to remain inactive while waiting for companies to knock on the door seeking negotiation. An active approach on negotiations according even to the institution's own outlined policy that permits an understanding of national and local requirements, has resulted in important benefits. The existence of a Business Development Office at INBio, with a highly qualified expert staff; attending seminars and activities with the industry; the distribution or sharing of information and material, and direct contacts, all enable an answer to be given, to a larger or smaller extent, to institutional challenges. The current policy is based on the idea that it is not enough to wait to be contacted, or be available at the behest of the company but to have and maintain one's own approach.

H. Understanding of national and local needs in terms of technology, training, and joint research. There is need for striking international strategic alliances. Even when an institution or community could possess adequate resources to face a concrete demand, knowing the national situation and the strategic needs will permit them to reach better agreements and fulfill a mission which transcends the mere satisfaction of the institution's interests. It will permit the prospecting to work in benefit of society as a whole and demonstrate that it is possible to improve the life quality of the same.

I. Macro policies and legal, institutional and political support. It has been pointed out that confronted with prospecting, the so called macro policies have to exist, (Sittenfeld and Lovejoy, 1998), that is to say, that clear rules on aspects related to what has been called the bioprospecting framework, which imply biodiversity inventories, information systems, business development, and access to technology, have to exist. One of the causes of the Costa Rican success is due, not only to the existence of institutions that have experience in negotiation, but also to the set of policies and actions that revolve around the same, such as a current biodiversity inventory which has been rated as successful and which enables us to know what we possess as the first step in the quest for making intelligent uses of this resource; the existence of a National Conservation Area System that assures the availability of resources; the possibility of future supplies and provisions; mechanisms that contribute to the conservation of the biodiversity, as part of the contractual systems, etc. At the same time, the possibility of possessing adequate instruments for the management of information, systems of land and property ownership, etc., contribute, jointly with the existing scientific capacity, to the creation of a favorable environment for bioprospecting and make possible the negotiation and attraction of joint enterprises.

To this must be added other elements, such as the existence of trustworthy partners, one of the most relevant aspects in joint undertakings (see Sittenfeld and Lovejoy, 1998).

Lastly, one of the crucial topics of these times has been the constant denouncement of the business community, due to the uncertainty that these new access rules are generating, mainly in terms of who is the competent authority, the steps that are to be taken, the way in which to secure prior informed consent, etc. The emergence of these new regimes, together with the fact that the intention is to essentially control genetic information, its flow, supply and reception, a topic where little national, regional and

international experience exists, has been a cause of concern due to the possibilities of contravening legal provisions. That has led to establish, as a policy, the inclusion of clauses related to the need of fulfilling local regulations, to demonstrate the contracting parties' right to fulfill their obligations pursuant to national laws, to present the appropriate permits and licenses, etc. In some cases, this topic has represented important discussions and analysis in agreements to be negotiated. At an international level, various bio-prospecting agreements around the world are being the target of complaints, claims and lawsuits, precisely due to the lack of legal certainty, and this has created problems, discrepancies, and it favors very little the carrying out of activities and joint ventures^[34]

[32] See Mateo, 1996 and Mateo, 2000

[33] See Ten Kate and Laird, 1999, in relation to this topic

[34] (For example, complains regarding the Agreement between Diversa and the Autonomous University of Mexico: between this company and Yellowstone Park, this last one recently solved in favor of the park; complains on the agreement signed between the Venezuelan Ministry of the Environment and the Federal University of Zurich, which involves a traditional knowledge of the Yanomamis, etc.).

[PKV1] What is ADN

[PKV2] What is ss

[PKV3] Should we say instead "maximm capacity for decentralisation and for defining legal instruments" ??

[PKV4] The earlier text says "This applies" What is applied??

[PKV5] What is CT? Ask the author to elaborate!

[PKV6] Not clear how can you extract rights from the impossibility of granting intellectual property rights???

[PKV7] what is DPI?

[PKV8] Is this word besides correct if added, check with the author.

[PKV9] Elaborate this, give detail of the abbreviation.

[PKV10] What is ADPIC Agreement?

VII. Conclusions

The Costa Rican case has shown interesting individual features that make it worthy of mention, although it does not necessarily constitute an example to be followed in other nations. Peculiar circumstances of the national reality (see Mateo 1996 for these special situations), the size of the country, the structure of the central government, its political, educational, and social situation, etc., have led to the establishment of important conditions of its own. It is an example of a nation that decided to take a road instead of continuing to discuss the difficulties that exist to travel on it. From this perspective, the practical experiences in access and benefit sharing that are embodied in contracts and collaboration treaties with the public and private sectors at the national and international levels; the creation of a Law of Biodiversity that seeks to answer the challenges made by the Convention; the regulation of general sui generis systems principles; etc., are all elements that enable us to have concrete proposals for generating a debate.

Possibly, this is the most valuable aspect of this experience.

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