

# **Biodiversity for (Bio)Technology under the Convention on Biological Diversity: Bioprospecting partnership in practice**

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## INTRODUCTION.

The importance of biotechnology for food, agriculture, human health, environmental protection, etc, has been outlined by diverse studies and emphasized by entities such as the Food and Agriculture Organization of the United Nations and the United Nations Environment Programme. At the same time, the access and acquisition of these technologies result especially complex due to their proprietary character, basically because of the existence of intellectual property rights such as patents and plant breeder's rights. In the great majority of cases, big transnational firms are the owners of these rights due to their financial capacity to destine important resources to the research and development of new products and biotechnological processes<sup>2</sup>.

In order to close this gap between those who have the control of these technologies and those who need them, especially developing countries, many different schemes have been essayed to facilitate the access and transfer of biotechnology, but mostly in the agricultural field. One of the most well-known to date has been the programme of the International Service for the Acquisitions of Agrobiotechnologies (ISAA), which is limited to the agricultural field.<sup>3</sup>

Another interesting option on this subject has taken place in Costa Rica, via the negotiations undertaken by the National Biodiversity Institute (INBio). Through agreements on access and supply of biodiversity (samples and extracts), important technology has been acquired (not all cases involve biotechnology) that has helped to consolidate a minimum infrastructure which allows the adding of value and the discovery of new intelligent uses for genetic resources. As a private, of public interest and non-profit institution, INBio has generated an important experience on the subject of sharing the benefits derived from the access to genetic resources since the signature of the Merck and C. Agreement in 1991.

This experience results illustrative of the manner in which the objectives of the Convention on Biological Diversity relative to the sharing of the benefits derived from access to genetic resources, including transference of technology, can truly be applied. In general, it shows the importance of collaborative agreements which allow our countries to access the technology and know-how necessary to add value to the elements of biodiversity and in this manner, contribute to their conservation and sustainable use, thereby improving the quality of life of the habitants.

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<sup>2</sup> In many occasions conflicts have even arisen because of patents granted to different firms which overlap or because the utilization of a product or process leads to confrontation with different patent holders, for example, for technology used, promoters, etc...

<sup>3</sup> See Krattiger, 2000

## INBIO EXPERIENCE<sup>4</sup>

The National Biodiversity Institute (INBio) was created in 1989 as a non-governmental, non-profit association for private founding members and it has been declared of public good. Its mission is to promote a new awareness of the value of biodiversity, and thereby achieve its conservation and use it to improve the quality of life.

In 1991, INBio developed the concept and practice of "bioprospecting" as one of the answers to the need of using, in a sustainable way, Costa Rican biodiversity to benefit society. This concept continues gaining acceptance in government, scientific, academic and managerial circles, and it refers to the systematic search of new sources of chemical compounds, genes, proteins, microorganisms and other products that possess a current economic value or potential and can be found in our natural biological wealth. The use of the biodiversity presents opportunities and challenges to promote and to organize the infrastructure investments and human resources that add value and contribute to its conservation.

INBio has a formal Agreement with the Ministry of the Environment and Energy (MEE), which allows carrying out specific activities of the national inventory and of use of the biodiversity in the government's protected areas. INBio develops biodiversity prospecting actively in the protected wild areas of the country under that agreement, with the participation of the national and international academic and private sector. Research is carried out in collaboration with investigation centers, universities and national and international private companies, by means of investigation agreements that include key elements, such as:

- Access: limited in time and quantity
- Equity and compensation: Research budget, Benefit sharing ( royalties and milestone, etc) ,Technology Transfer,
- Training
- Non-destructive activities
- Up front payment for conservation

The agreements specify that 10% of the research budgets and 50% of the future royalties are donated to the Ministry of the Environment and Energy (MEE) to be reinvested in conservation. The research budget supports the scientific infrastructure in the country, as well as activities of added value aimed to conservation and sustainable use of the biodiversity. Up to now no

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<sup>4</sup> Based on information provided by the Bioprospecting Unit of INBio.

royalties have been paid or any product has reached the market but there are some products under development, especially related to ornamental and herbal areas.

Next, a brief summary of the most outstanding investigation agreements is presented.

#### **Research Collaboration Agreements with the industry:**

##### ***INBio-Merck Agreement: Search of sustainable uses of the Costa Rican biodiversity.***

It was the first agreement signed with a commercial company (October of 1991) for the search of sustainable uses of the Costa Rican biodiversity with potential for the pharmaceutical industry and veterinary science. It was renewed in 1994, 1996 and 1998; in similar terms. This agreement comprised the study of a limited number of extracts of plants, insects and environmental samples for the elaboration of extracts to determine its potential use. The agreement has allowed INBio to have access to technology, team and training.

##### ***Chemical prospecting in a Costa Rican Conservation Area:***

This project began in 1993 and it finished in September of 1999. It is one of the five International Groups of Cooperation in Biodiversity (ICBG's) of the world financed by the National Institutes of Health (NIH) of United States. It was located in the Guanacaste Conservation Area and was carried out in collaboration with the University of Costa Rica, the University of Cornell and Bristol Myers Squibb. Its objectives were the incorporation of the tropical insects in the processes of search of new pharmaceutical products and to increase the capacity of the human resource in the fields of the ecology, the taxonomy and the ecochemistry.

##### **INBio-Givaudan Roure Agreement: Fragrances and aromas,**

As a result of the constant search of new options, in 1995 INBio began in association with the company Givaudan-Roure a phase of exploration of potential fragrances and aromas from our biodiversity. The aromas and the fragrances were taken directly of the air of the forest that is in contact with fragrant objects. The objective was to determine the feasibility of new products from volatile compounds of the Costa Rican biodiversity and the technology transfer in this area. A royalty rate was established. This agreement concluded its activities in Costa Rica by the middle of 1998.

## **INBio-BTG-Ecos La Pacífica Agreement**

In the agricultural area, INBio seeks to integrate the result of the bioprospecting activity with the economic development of the country. This process began with the signature of the INBio-British Technology Group (BTG) Agreement in 1992, that allowed INBio to begin the investigation, characterization and production of a product with nematocidal activity (DMDP) coming from a tree of the Costa Rican dry tropical forest. Parallely, investigations have been developed jointly with the corporation Ecos La Pacífica, aiming to determine the growing conditions of the species and the production of the DMDP, as well as the effectiveness of this nematocide in tropical crops. The greenhouse and field trials for began in 1999 and they continue being carried out to date with very satisfactory results. BTG has paid an small amount of money to both INBio and Ecos due to the licensing of a patent related to the DMDP use.

## **INBio-Diversa Agreement: Search for enzymes from extremophilic organisms with application on Chemical Industry.**

For the exploration of new enzymes in aquatic or terrestrial microorganisms of the Costa Rican biodiversity under extreme conditions, INBio signed a research agreement with the DIVERSA biotechnical industry in 1995 and renewed it in 1998 and in 2002. It involves the gathering of bacteria in different Conservation Areas of our country that will be studied for the identification and the isolation of new useful enzymes in the industry. The agreement also guarantees the training of Costa Rican scientists in collection methods, isolation and molecular biology, specifically in cloning and characterization of genes associated to enzymes.

## **INBio-INDENA S.P.A. Agreement: Search for compounds with antimicrobial and antiviral activity.**

With the objective of obtaining compounds with antimicrobial potential to be used as active ingredients in cosmetics, INBio and the phytopharmaceutical company INDENA, with headquarters in Milan, Italy, signed an collaboration agreement in 1996, with a second phase that started in 2000. Extracts selected of plants are evaluated in bioassays to determine their antimicrobial activity. The final process is carried out in INDENA.

## ***INBio-Phytera Inc. Agreement***

Traditionally drugs have been developed starting from extracts of leaves, roots, bark and other parts of the plants. Today, with the advances in the biotechnology, they can be derived cultivations of cells starting from extremely small samples and to induce the production of a diversity of chemical substances in these cultivations, higher than when the original plant is used. In 1998 INBio signed an Agreement with this company, which was executed until the year 2000.

### **INBio- Eli Lilly Agreement: Search of new compounds.**

This project started in 1999 and it concluded in the year 2000. It was carried out with the pharmaceutical company Eli Lilly and Co. and its objective was the search of botanical compounds with pharmaceutical application. As a result of the successful collaboration Ely Lily donated to INBio modern technology for the preparation of fractions ( the Bioexplore). This technology transfer allows INBio to provide fraction services and to improve its research and development capabilities for adding value to the biological diversity.

### ***INBio-Akkadix Corporation Agreement: Search for compounds with nematocidal activity.***

This project was carried out with the company Akkadix Corporation and was carried out from 1999 to 2001. Its main objective was the search of alternatives for the control of nematodes.

### **I. Agreements with the Academia**

There are also, agreements of academic investigation with national and international universities. These agreements vary considerably in their focus but all they are guided toward the solution of problems and the search of knowledge and products.

### **INBio-University of Strathclyde Agreement**

This agreement allows the access to new technologies and methodologies, as well as the interaction, through the University of Strathclyde, with the Japanese private sector. INBio provides a limited number of extracts of plants to also be evaluated during a time limited by several industries of that country. This agreement was developed from 1997 to 2000.

### **INBio-University of Massachussets Agreement: Search for potential insecticides**

Through a collaboration with the University of Massachusetts in U.S.A. thanks to the support of the National Institutes of Health (NIH), we carried out a research looking for compounds with insecticidal activity.

This investigation began in October of 1995 and it concluded in 1998. Its objective was the realization of enzymatic bioassays of extracts coming from plants, insects, bryophytes and mollusks.

### **INBio- University of Guelph Agreement: Development of New Technologies for Medicines based on Plants, an International Interdisciplinary initiative**

This agreement is carried out with the University of Guelph. It was signed in the year 2000 and it will extend until the year 2003. Their main objective is the search of new pharmaceutical products through technical such as cultivation of tissues from plants.

## **II. Other Agreements**

### **Validation of promissory plants**

This project was financed by CR-USA Foundation. It contemplated 3 sub-projects that allowed to obtain information to improve the quality of life of the Costa Rican. In collaboration with the CIDPA ( Center for Research and Diagnosis in Parasitologia of the University of Costa Rica) two plants were studied to isolate active components against malaria. This investigation allowed to give continuity to the most excellent results in the ICBG project.

Also, in collaboration with the UME (Unit of Electronic Microscopy), LEBI (Laboratory of Biological Assays) and the National Children's Hospital, those plants were validated traditionally for the gastritis treatment by their activity anti-helicobacter pylori. Finally some species were validated by their alkaloid content to explore their economic feasibility.

### **The Chagas Project**

INBio jointly with EARTH, the National University of Costa Rica and other Latin American institutions of Brazil, Mexico, Chile, Argentina, Uruguay and the NASA of United States, are part of "The ChagaSpace Project", an investigation proposal that would help to look for solution to one of the most serious problems in public health of Latin America: the Chagas disease or American Tripanosomiasis. INBio carried out some search activities on plants with inhibitory activity of the disease in 1997. In the year 2001 the United States of America Congress approved a fund dedicated to finance this project again, which has allowed to restart the bioassays.

### **INBio-IDB Agreement: Program from Support of the Development of the Use of the Biodiversity by Small Enterprises**

In February of 1999, INBio signed an agreement with the Interamerican Development Bank with the purpose of formalizing the terms of the grant of a non reimbursable technical cooperation, to support the development of the use of the biodiversity by small companies.

6 projects have been approved, as follows:.

1. Agrobiot S.A.: Propagation of Costa Rican tropical plants to be commercialized as eco-educational souvenirs;
2. Laboratorios Lisan S.A.: Pharmaceutical products based on medicinal plants : at least 5 natural products to be commercialized in 2004 and 2005;
3. La Gavilana: Development of a model of eco-friendly practices for vanilla production: a biopesticide was identified allowing the organic production of the vainilla.
4. Industrias Caraito S.A.: Generation of added value on the Carao agro-industry.
5. Bougainvillea S.A.: Research for development and production of a Biocide from Quassia amara wood;
6. Follajes Ticos S.A.: Ornamental plants native from the forest and with possibilities to be successfully commercialized: Several new species are under domestication.

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. 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 four following table summarices the main collaborative agreements, benefits and research results.

**Table 1. Most significant Research Collaborative Agreements with Industry and Academia.**

### III. Period 1991-2002

Industry or Academic partner	Natural resources accessed or main goal	Application fields	Research activities in Costa Rica
Cornell University	INBio's capacity building	Chemical Prospecting	1990-1992
Merck & Co	Plants, insects, micro organisms	Human health and veterinary	1991-1999
British Technology Group	DMDP, compound with nematocidal activity*	Agriculture	1992-present
ECOS	<i>Lonchocarpus felipei</i> , source of DMDP*	Agriculture	1993-present
Cornell University and NIH	Insects	Human health	1993-1999
Bristol Myers & Squibb	Insects	Human health	1994-1998
Givaudan Roure	Plants	Fragrances and essences	1995-1998
University of Massachusetts	Plants and insects	Insecticidal components	1995-1998
Diversa	DNA from Bacteria	Enzymes of industrial applications	1995-present
INDENA SPA	Plants*	Human health	1996-present
Phytera Inc.	Plants	Human health	1998-2000
Strathclyde University	Plants	Human health	1997-2000
Eli Lilly	Plants	Human health and agriculture	1999-2000
Akkadix Corporation	Bacteria	Nematocidal proteins	1999-2001
Follajes Ticos	Plants	Ornamental applications	2000-present
La Gavilana S.A.	<i>Trichoderma</i> spp *	Ecological control of pathogens of <i>Vanilla</i>	2000-present
Laboratorios Lisan S.A.	None*	Production of standardized phytopharmaceuticals	2000-present
Bouganvillea S.A.	None*	Production of standardized biopesticide	2000-present
Agrobiot S.A.	Plants*	Ornamental applications	2000-present
Guelph University	Plants*	Agriculture and Conservation purposes	2000-present
Florida Ice & Farm	None*	Technical and scientific support	2001-present
ChagasSpaceProgram	Plants, fungi*	Chagas disease	2001-present

SACRO	Plants*	Ornamental applications	2002-
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- These agreements involve a significant component of technical and scientific support from INBio. Source, Tamayo et al forthcoming 2003.

**Table 2.** Monetary and Non Monetary Benefits of Bioprospecting.

<b>Monetary Benefits</b>	
	<ul style="list-style-type: none"> <li>* 100 % of research budgets</li> <li>* Technology transfer and infrastructure</li> <li>* Up front payments for Conservation</li> <li>* Significant contribution for GCA and Universities</li> <li>* Milestone and royalty payments to be shared with MINAE</li> </ul>
<b>Non Monetary Benefits</b>	
	<ul style="list-style-type: none"> <li>* Trained human resources</li> <li>* Empowerment of human resources</li> <li>* Negotiations expertise developed</li> <li>* Market Information</li> <li>* Improvement of local legislation on conservation issues</li> </ul>

**Table 3.** Outputs generated since 1992 as a result of RCA with INBio. Source, Tamayo et al 2003

Project	Initiated	Output*
Merck &	1992	27 patents

<b>Co.</b>		
<b>BTG/ECOS</b>	<b>1992</b>	<b>DMDP on its way to commercialisation</b>
<b>NCI</b>	<b>1999</b>	<b>Secondary screening for anti-cancer compounds</b>
<b>Givaudan Roure</b>	<b>1995</b>	<b>None yet</b>
<b>INDENA</b>	<b>1996</b>	<b>2 compounds with significant anti-bacterial activity</b>
<b>Diversa</b>	<b>1998</b>	<b>2 potential products at initial stages / Publication underway</b>
<b>Phytera Inc.</b>	<b>1998</b>	<b>None yet</b>
<b>Eli Lilly &amp; Co.</b>	<b>1999</b>	<b>None yet</b>
<b>Akkadix</b>	<b>1999</b>	<b>52 bacterial strains with nematocidal activity</b>
<b>CR-USA</b>	<b>1999</b>	<b>1 compound with significant anti-malarial activity</b>
<b>LISAN</b>	<b>2000</b>	<b>2 phytopharmaceuticals in the process</b>
<b>Caraito</b>	<b>2000</b>	<b>None yet</b>
<b>Follajes ticos</b>	<b>2000</b>	<b>None yet</b>
<b>Bougainvillea</b>	<b>2001</b>	<b>None yet</b>
<b>La Gavilana</b>	<b>2001</b>	<b>None yet</b>
<b>Agrobiot</b>	<b>2001</b>	<b>None yet</b>
<b>SACRO</b>	<b>2002</b>	<b>None yet</b>

Source: Tamayo et al, 2003.

The following table enumerates de contributions by the INBio derived from the bioprospecting agreements that the Institute has signed.

<b>Contribution to Biodiversity Conservation in Costa Rica and to Universities:</b>	<b>1993*</b>	<b>1994</b>	<b>1995</b>	<b>1996</b>	<b>1997</b>	<b>1998</b>	<b>1999</b>	<b>2000</b>	<b>Total</b>
Ministry of Environment and Energy (MINAE) by 10%	110,040	43,400	66,670	51,092	95,196	24,160	38,793	82,797	512,148
Conservation Areas (Development of Bioprospecting Research)	86102	203,135	153,555	192,035	126,243	29,579	0	0	790,649
Costa Rican Public Universities	460,409	126,006	46,962	31,265	34,694	14,186	7,123	4,083	724,728
Other groups in INBio	228,161	92,830	118,292	172,591	129,008	0	0	0	740,882
<b>Total</b>	<b>884,712</b>	<b>465,371</b>	<b>385,479</b>	<b>446,983</b>	<b>385,141</b>	<b>67,925</b>	<b>45,916</b>	<b>86,880</b>	<b>2,768,407</b>
<b>*Estimated amounts since 1991</b>									

### **Some legal considerations.**

In Costa Rica the genetic and biochemical resources are property of the State due to qualification like goods of public domain, independently that they are in private lands, in indigenous territories or the property rights on the biological resources that possess the owners. In the cases of indigenous territories, public or private owners of the lands or the biological resources containing them, it is required the prior informed consent of the owners, in order to allow the access, without granting them a right of property on the genetic and biochemical components, as it will be explained later on. In this sense, law requires the applicant of the access to attach the prior informed consent, granted by the owner of the land where activity will be developed, by the authority of the indigenous community when it is in its territories or the Director of the Area of Conservation. (Article 65 Law of Biodiversity).

The Law of Biodiversity of Costa Rica, No 7788 of 27 May 1998 is applied to the components of the biodiversity that are under the sovereignty of the State, as well as to the processes and activities carried out under its jurisdiction or control, independently from those effects manifested inside or outside of the national jurisdiction. This Law shall specifically regulate the use, management, associated knowledge and sharing of the benefits and derived costs of the utilization of the biodiversity

components (Article 3). Also, Article 6 (public domain) it establishes that biochemical and genetic properties of the components of the wild or domesticated biodiversity belong to the public domain. The State will authorize the exploration, research, bioprospecting, use and utilization of biodiversity components which constitute part of public domain, as well as the use of all the genetic and biochemical resources, through access standards established in the Chapter V of this Law. Likewise, in accordance with Articles 62 and 69, all research or bioprospecting program on genetic or biochemical material of biodiversity aim to be carried out in the Costa Rican territory requires an access permit, unless they are covered for some of the exceptions provided for this Law. These exceptions (Art 4), are basically referred to access to human genetic resources; the exchange of genetic and biochemical resources and the traditional associated knowledge resulting of traditional practices of indigenous peoples and local communities, when they are non profit; and the Public Universities which had the term of one year (up to May 7 1999<sup>5</sup>) to establish their own controls and regulations for their researches that imply access and be non profit. If it were not so, all the sectors (pharmaceuticals, agricultural, crop protection, biotechnology, ornamental, herbal, etc) accessing to genetic component are subject to the application of the Law and they should follow the access procedures.

In this regard the access regulations are applied to genetic resources in public or private lands, terrestrial or marine environments, under *ex situ* or *in situ* conditions and in indigenous territories<sup>6</sup>. Likewise, relevant access provisions of the Law are applied to indigenous territories, but additionally the own rules of these peoples should have into account, as well as the *sui generis* community intellectual rights. Similarly it is recognized to communities and indigenous peoples the right to oppose the access to their resources and associated knowledge, for cultural, spiritual, economic reasons, or of another kind of reasons.

*Box 1* provides the difficulties and challenges of implementing legal frameworks in the case of Costa Rica

**Difficulties and challenges of implementing Legal Frameworks, the case of Costa Rica:**

<sup>5</sup> Only the University of Costa Rica developed their own Regulation of Access

<sup>6</sup> Article 2 (Area of application) of the Draft Regulations on Access states that it shall be applied on genetic and biochemical elements of wild or domesticated biodiversity, *in situ* or *ex situ*, under State Sovereignty, that are public or private propriety.

Costa Rica enacted in 1998 the Biodiversity Law. The Law regulates the access to genetic and biochemical resources and the sharing of the benefits arising out of their utilization. This Chart summarizes the main difficulties and challenges that Costa Rica has faced in the process of developing the Biodiversity Law.

### **Uncertainty and value**

- Bio-prospecting is very uncertain; the word bioprospecting has been derived from prospecting for oil and minerals, but bioprospecting, or prospecting for biological or genetic resources and even of indigenous knowledge, is quite different, because it presents even greater risks; only a few products have reached the clinical or even pre-clinical stage, even though a lot of samples have been collected from all over the world since the mid-1980s.
- When determining the value of genetic resources, it should furthermore be born in mind that the significance of one sample in the overall chain of efforts and costs to develop a new product or a new drug is very limited. Unless a country can add value to these resources, for instance by scientific research, their value, and therefore the benefit that can be obtained has the potential to increase.

- Technology has had a paradoxical impact on the value of biological resources. On one hand, new technologies increase the potential commercial use, and therefore the economical value, of biological resources, while the cost of screening these materials and/or isolating active ingredients is decreasing. On the other hand, technological developments have reduced the amount of material needed for research purposes, and may thereby have facilitated illegal collection and use. So while, in general, the economic value of genetic resources is increasing, the commercial value of any particular extract or sample is not.

### **Rights and ownership**

Property rights and ownership: the CBD does not address the question of ownership; it only establishes (Article 3) that states are sovereign over their genetic and biological resources. But sovereignty, national patrimony and ownership are different concepts; therefore, it is important to clearly define ownership in the national law. In fact some of the most common problems arising when negotiating benefit-sharing agreements are related to the lack of clarity on ownership. In Costa Rica, the Law divides the property rights of biodiversity into genetic and bio-chemical properties and the biological resources *per se*: the biochemical and genetic properties belong to the State,

therefore are under the administration of the Ministry of the Environment and Energy, while, biological resources are the property of the land owner, a situation that causes confusion and debates around definitions and intention of use.

### **Over-regulation**

#### **Another notorious pitfall is over-regulation:**

- The complexity of access regulations creates problems; if nobody can comply with the regulations, most likely they will be not enforced. High transaction costs and bureaucratic procedures contribute to a lack of enforcement.
- Access legislation may negatively affect basic research; it may have negative impact on local universities and research institutions, as basic research is important for conservation purposes and for sustaining biodiversity.

#### **Defeating the purpose?**

The ultimate goal of access and benefit sharing should be clear. If the main aim is to make money, it is bound to fail. In case the objective is to create national capacity, a value added industry, or the conservation

of natural biological resources, then it is necessary to make the right connections, and develop coherent policies on access, biodiversity conservation and sustainable use. These policies should include access to knowledge and traditional use of medical products. Considerations on different treatments or regulations according to the initial nature or purpose of research: non commercial versus research intended for commercial development, has produced discussions on whether or not to consider all kinds of intended research with a potential for sending sooner or later, products to the market place.

Source: Sittenfeld, Cabrera y Mora, 2003.

## LESSONS LEARNED

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, 1997) 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 Traditional knowledge 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 access and benefit sharing 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.<sup>7</sup> 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.

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<sup>7</sup> See Ten Kate and Laird, 1999, in relation to this topic

**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<sup>8</sup>

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<sup>8</sup> (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; complaints on the agreement signed between

## 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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