Article

Biodiversity for (Bio) technology under the convention on biological diversity: Bioprospecting Parternship in practice

By

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INTRODUCTION

La importancia de la biotecnología para la alimentación, la agricultura, la salud humana, la protección del ambiente, etc ha sido destacada por diversos estudios y enfatizada por entidades tales como la Organización De Naciones Unidas para la Agricultura y la Alimentación, el Programa de Naciones Unidas para el Medio Ambiente, etc. Al mismo tiempo, el acceso y adquisición de estas tecnologías se presentan especialmente complejo debido al carácter propietario de las mismas, fundamentalmente por la existencia de derechos de propiedad intelectual, tales como patentes y derechos de obtención vegetal. En la gran mayoría de los casos, grandes empresas transnacionales son las titulares de estos derechos, dado que son las únicas con la capacidad financiera para dedicar cantidades importantes de recursos a la investigación y el desarrollo de nuevos productos y procesos biotecnológicos.[1]

Precisamente para cerrar la brecha entre quienes poseen el control de estas tecnologías y quienes las necesitan especialmente en países en desarrollo, se han ensayado diferentes esquemas para facilitar el acceso y la transferencia de biotecnología, fundamentalmente en en el campo agrícola. Uno de los más conocidos ha sido el programa del International Service for the Adquisitions of Agrobiotecnologies (ISAA), limitado al campo agropecuario.[2]

Otra de las formas como la misma se ha materializado en Costa Rica ha sido a través de las negociaciones emprendidas por el Instituto Nacional de Biodiversidad mediante contratos, los cuales mediante el acceso y suministro de biodiversidad (muestras y extractos) han permitido adquirir importante tecnología (aunque no en todos lo casos se trata de biotecnología) y consolidar una infraestructura mínima que posibilite agregar valor y descubrir nuevos usos inteligentes para los recursos genéticos. Como una institución privada, de interés público y sin fines de lucro el INBio ha generado una importante experiencia en el tema de distribución de beneficios derivados del acceso a recursos genéticos desde la firma del Convenio con Merck and Co en 1991.

Dicha experiencia resulta ilustrativa de la forma como los objetivos de la Convención sobre la Diversidad Biológica relativas a la distribución justa y equitativa de los beneficios derivados del acceso a los recursos genéticos, incluyendo la transferencia de tecnología, pueden ser realizados en la práctica. En general, muestra la importancia de los acuerdos de colaboración que permitan a nuestros países el acceso a la tecnología y al know how necesario para agregar valor a los elementos de la biodiversidad y contribuir así a su conservación y uso sostenible en beneficio de la calidad de vida de los habitantes.

INBIO EXPERIENCE

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 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.

a. Academic agreements with Universities and other research centers (University of Costa Rica, National University, Strathclyde, Massachussets, 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 Fragances, 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 nomatocidal 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 three following tables summarices the main collaborative agreements, benefits and research results.

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

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	*Lonchocarpus felipei*, 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.	*Trichoderma* spp *	Ecological control of pathogens of *Vanilla*	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-

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.

Monetary Benefits
*** 100 % of research budgets** *** Technology transfer and infrastructure** *** Up front payments for Conservation** *** Significant contribution for GCA and Universities** *** Milestone and royalty payments to be shared with MINAE**
Non Monetary Benefits
*** Trained human resources** *** Empowerment of human resources** *** Negotiations expertise developed** *** Market Information** *** Improvement of local legislation on conservation issues**

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

Project	Initiated	Output*
Merck & Co.	**1992**	**27 patents**
BTG/ECOS	**1992**	**DMDP on its way to commercialisation**
NCI	**1999**	**Secondary screening for anti-cancer compounds**
Givaudan Roure	**1995**	**None yet**
INDENA	**1996**	**2 compounds with significant anti-bacterial activity**
Diversa	**1998**	**2 potential products at initial stages / Publication underway**

Phytera Inc.	1998	None yet
Eli Lilly & Co.	1999	None yet
Akkadix	1999	52 bacterial strains with nematocidal activity
CR-USA	1999	1 compound with significant anti-malarial activity
LISAN	2000	2 phytopharmaceuticals in the process
Caraito	2000	None yet
Follajes ticos	2000	None yet
Bougainvillea	2001	None yet
La Gavilana	2001	None yet
Agrobiot	2001	None yet
SACRO	2002	None yet

Source: Tamayo et al, 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, 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 that 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 bogusness 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.[3]. 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[4]

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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[1] En muchas ocasiones incluso se han presentado conflictos debido a que patentes otorgadas a diferentes empresas se traslapan entre sí o bien la utilización de un producto o proceso conlleva enfrentarse a distintos dueños de patentes, por ejemplo sobre la tecnología utilizada, promotores, etc.

[2] Véase al respecto Krattiger, 2000.

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

[4] (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 the Venezuelan Ministry of the Environment and the Federal University of Zurich, which involves a traditional knowledge of the Yanomamis, etc.).