The contractual regulation of access to biological resources and genetic plant information: an agreement between Mexican communities and a multinational bio-prospecting concern

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Abstract

The paper deals with the question of the ownership, use and protection of biological resources with a high potential market value. While the Convention on Biological Diversity has been developed at international level to halt the rapid loss of biodiversity (international regime), bottom-up approaches also exist whereby communities negotiate with bio-prospecting multinational firms.
The paper analyses a success story in Mexico wherby Sandoz, a multinational Swiss chemicals concern, concluded a contract with four Mexican communities governing the access to and use of raw plant material. The contract and process surrounding its establishment are studied and questions such as the appropriate consideration of local people, access and the sharing of benefits are examined. The paper concludes with an account of the conditions necessary for knowledge transfer and the success of bio-prospecting agreements.

Keywords: property and use rights, biodiversity, bio-prospecting, contract, access and benefit sharing, knowledge transfer, Mexico

0. Introducton

Thanks to the adoption of the Convention on Biological Diversity (CBD) at the United Nations Conference on Environment and Development in Rio de Janeiro in 1992, biodiversity prospecting (bio-prospecting) has become a feasible solution for the creation of economic incentives for the preservation of biodiversity. Bio-prospecting is the systematic research, collection and appropriation of biota for new commercial applications. The fair and equitable sharing of benefits arising from the utilization of genetic resources is a major goal of the CBD. Over the past ten years, national and international policymakers have been dealing with the questions surrounding the access to and use of genetic resources for commercial and scientific purposes, particularly by pharmaceutical industry.
There are very few agreements throughout the world that could be considered as a success by the relevant stakeholders. One such agreement is the Novartis-Biolead Agreement, which is particularly interesting because it demonstrates that it is possible for a pharmaceutical giant like Novartis and group of small communitites to collaborate successfully.
We start in Part 1 of our study with an exploration of the relevant theoretical elements: genetic resources are defined and property rights presented as an important steering dimension. We also summarise the definition of property rights and access and benefit

sharing by international law. Part 2 deals with the case study, provides a description of the stakeholders, the process and the access and benefit sharing (ABS) contract. Part 3 provides an overview of the conditions for success and the tranferability of the biolead experience gained in the BioLead project.

1. Theoretical background and international agreements

1.1 Protection of genetic information by defining property and use rights and making agreements

The special nature of biodiversity makes it extremely difficult to determine its monetary value. Biological diversity is defined as the variability among living organisms from all sources (CBD Article 2). Biodiversity as a resource provides a lot of goods and services with different characterics. Table 1 contains an overview of the different categories (components) of value of biodiversity.

Direct use value	Food and fibres, building and industrial material/Fuel/Medicines for local people/ Pharmaceuticals/Agricultural inputs: genes, pesticides, microorganisms/Recreation
Indirect use value	Habitat for plants, animals and micro-organisms/Habitat for migratory species/ Watershed protection/Soil protection/Storage and recycling of human produced wastes/Carbon storage/Climate regulation/Medicine; model for synthetic copying of natural active molecules
Option value	The option for any direct or indirect use in the future (e.g. medical, agricultural, industrial, climate control needs)
Quasi option value	The value of information held in conserved resources
Bequest value	The value placed by some people on bequething resources for future generations
Existence value	The value placed by some people on the existence of a biodiversity they never expect to see or to use (e.g. the value of knowledge that Siberian tigers survive).

Table 2: Categories of Values of Biodiversity (drawn from Day-Rubenstein (2001:211). See also OECD (1999:28-31)).

The goods and services provided by biodiversity are valuable but unlikely to generate economic return. Therefore, the nature of the goods and services in question explains why the preservation of the resource is unlikely. Goods, for which the exclusion principle for beneficiaries is not applied, and for which rival uses exist, present particular problems. The cost of the creation of regulations for the exclusion of potential users is relatively high in this instance and this, naturally, prompts the users to overexploit the resource. Ostrom refers in this context to "*common pool resources*".

The fact that biodiversity is closely linked to the preservation of land is another argument in this context. An incentive for conservation only exists if the benefits from preservation are the equal to or even greater than those forces leading to the conversion of the land for other purposes. While the costs of preserving lands are immediate, the benefits are long term and diffuse.

Several authors (Pearce/Moran, Day-Rubenstein, Swanson) agree that the differences between individual and private benefits and the social values of biodiversity represent an important obstacle to the preservation of biodiversity. Decisions on land conversion are influenced by the private returns. When the benefits mostly accrue at national and international level, conservation of land and biodiversity is questioned and the positive

external effects will diminish. The economics literature refers to this phenomenon as external effe effects.

In addition to the characteristics of goods as possible explanations for the degradation of resources, the literature also refers to non-defined property rights and the prisoner's dilemma. To put it simply, these approaches share the basic idea that due to individual actor interests and the associated optimisation of use, the free-rider problem becomes an obstacle to the socially desired production of public rules and goods. For nobody can be excluded from the use of the collective goods once the goods in question have been produced and thus it is impossible to find a voluntary producer. However, Feeny et al. (1990: 12) draw attention to the fact that "... complex interactions among characteristics of the resource, the property rights regime and other institutional arrangements, and the socio-economic environment contribute to the degree of management success".

How can the degradation of biodiversity be halted? Central economic concepts focus on the internalisation of external effects and the design of institutional mechanisms for coping with social dilemmas. In contrast to the Pigouvian Tax solution (Pigou 1962), Coase (1960) assumes that property and use rights must be clearly regulated to enable effective and efficient use and management of resources. In his opinion, it is irrelevant who actually owns these rights as the use which yields most profit will always prevail.

If the external effects are not integrated on a market basis, Pareto efficiency no longer exists. Coase proposes in this case that the external effects be internalised using property rights, and that the property rights be adapted on this basis. This presupposes that the rights are specified and the freedom exists to exchange title and undertake the corresponding adaptations. Internalisation will only be possible as part of a two-tier process. Firstly, the legal title is specified; if the transaction costs are zero, it is of no importance for the allocation of resources who receives the legal title. Secondly, the rights can then be exchanged. They are traded until the marginal utility of the transfer of title corresponds to the marginal cost or until a Pareto-efficient allocation of resources is achieved. This is the central message of the Coase theorem. The internalisation process can be demonstrated, for example, for the resource air: although the space above landed property is in the hands of the property owner, the owner cannot dispose of it freely. Thus, it is at least unclear in part whether each individual has a right to clean air or to air as a medium of absorption of pollutants. The state can thus prohibit all air pollution or allow air pollution. In the former case, producers would try to exchange air pollution quotas for money, or persons suffering from breathing difficulties would try to reduce air pollution through the payment of compensation for restrictions in production.

The analysis of property rights and economic theory of contract, in particular, contribute to the analysis in the institutional economics literature. While the former concentrates on the question as to the form the definition and distribution of legal title should take and how their regulation affects the welfare of a society, the theory of contract examines how property righst can be exchanged with the help of contracts.

How can we define property rights and how should they be designed? Property, disposal and use rights can be understood as a social relation defining the title holder with regard to something of value against all others. Bromley speaks of "triadic social relation involving benefit streams, rights holders and duty bearers". "Rights can only exist when there is a social mechanism that gives duties and binds individuals to those duties. [...] Notice that rights only have an effect when there is some authority system that agrees to defend a rights holder's interest in a particular outcome" (Bromley, 1991: 15). A system of property rights could be regarded as a system with communicational vessels of claims and obligations, which means that allowing a specific behaviour to one actor implies a restriction on the behaviour of another actor.

Different types of property rights exist for natural resources. When these property rights have similar characteristics, they are referred to as a property-rights regime.[1] Their classification is based on different criteria (Bromley 1991; Libecap 1993; Ostrom 1990) which include title to property, organisation of exclusion, access control and decision-making processes within the regime. A distinction is made in the literature between four classical types of regimes: no property, common property, state property and private property.

In the case of private property, exclusive title to property is in the hands of private individuals or corporations and this must be respected by all others who are interested in the use of this property. The enforcement of rights is guaranteed by the state. In the case of no property (*res nullius*), we have a classical case of resources, for which access is not formally regulated. Common property and open access ("no property") were thrown together for a long time in the literature and this led to the misleading conclusion that collective ownership in the sense of the "Tragedy of the Commons" (Hardin 1968) would lead to the destruction of the resource. It has now been established, however, that in such cases of collective ownership, the resource in question is controlled and managed by an identifiable group. Moreover, the group establishes rules governing the use of the resource. Thus, common property can also be described as group private property (Bromley 1991; Libecap 1993; Ostrom 1990).

Table 2: Bundle of property rights

Type of ownership	Definition
State property	Exclusive title in the hands of the state: local, provincial, regional, national levels Access control by the state Decision-making by administration or state agency
Private property	Exclusive title in the hands of individuals and corporations Access control by individuals backed by the state Decision-making by individuals/corporations
Common property	Exclusive title in the hands of groups/corporations Possibility of exclusion of non-owners Access control by group, corporation backed by the state Decision-making by group/corporation
No property (*res nullius*)	Titles in the hands of nobody/everybody

[1] Devlin/Grafton (1998: 39) have the following to say on this matter: "Often property rights that have a similar set of characteristics are called property-rights regimes. The nature of these regimes is determined by the institutional setting, technology, and the aspect of the environment over which they are held."

The institutional economics literature also shows that there is no theoretical or empirical justification for the belief that the private property system *per se* is better than the other regulative systems.[2] Devlin/Grafton (1998) state that there is no "best" regulation and that a mix of regimes can be found in most cases and environmental destruction can be found in all regimes. However, it is possible to identify conditions for the success of specific regulative systems.[3] The exchange of rights is executed using contracts which regulate access and benefit sharing.

1.2. Legal framework

In the context of the considerations outlined above, from the legal point of view the following questions need be asked:

- How are the property and use rights regulated?
- On that basis who is entitled to grant access to the resources?
- How is the exchange system organised?

These questions should be asked from the perspective of the efficiency of the system in creating incentives to prevent decisions that give rise to harmful land conversion and thus foster the conservation of biological resources.

The parties involved in the negotiations leading to the BioLead agreement were Sandoz and the communities. It would appear that no state representative was involved in any capacity.

Access to biological or genetic resources (and their associated traditional knowledge) are regulated at international level by the Convention on Biological Diversity (CBD).[11]Access to such resources at domestic level is defined by the recent FAO Treaty on Plant Genetic Resources for Food and Agriculture (IT).[12]

In order to answer the questions raised above, some background information on the CBD will be provided, with an emphasis on its basic decisions with respect to the ownership of genetic resources; the regulation of access to genetic resources will also be described.

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2 "It should never be assumed that private-property systems are superior to common-property or state-property systems in either an economic, ecological or social sense". (Devlin/Grafton 1998: 39)

3 Devlin/Grafton (1998: 138) state: "The key to success is to set up an incentive structure for individuals that is compatible with both the characteristics of the resource and institutions." Thus, there is no sense in introducing private fishing rights in Africa when a collective system already exists.

11 Convention on Biological Diversity, adopted on 5 June 1992 on the occasion of the United Nations Conference on Environment and Development (UNCED), 3-14 June 1992, Rio de Janeiro , Brazil.

12 International Treaty on Plant Genetic Resources for Food and Agriculture concluded by the 31st conference of the Session of the FAO Conference, 3 November 2001.

CBD: context and basic decisions taken

The CBD was concluded at the Earth Summit on Environment and Development in Rio de Janeiro in 1992. The original goal of its initiators was to create an umbrella convention to consolidate existing "piecemeal" conventions for the conservation of biodiversity (Glowka et al, 1994). However, new findings and insights that arose in the course of the negotiation of the convention in the 1980s had fundamentally changed the perception of the concept of "biodiversity".

New biotechnologies and accomplishments in robotics had triggered profound changes in agricultural and pharmaceutical industries and new insight into the use of plant and animal genetic resources. In pharmaceutics, robotics and improvements in the efficiency of screening methods were increasingly enabling the testing of smaller samples in significantly reduced time and cost frames.

This led to a better understanding of the value of genetic information and to an increase in bioprospecting activities, which were regarded either as a form of "piracy" or as an option for making use of the "green petroleum" capable of bringing wealth to the gene-rich but financially poor countries of the Southern Hemisphere. Simultaneous developments in biotechnology resulted in a stimulation of the evolution of the intellectual property-rights system, enabling the inclusion of genes and plants into the patenting system.

This in turn led to a new debate on the equity of intellectual property rights. The continuing discussion about the balance between the rights of the creator and society as the user of his creation was now supplemented by discussions about the balance of rights between the creator and society as the *provider of the resources* which are utilised in the creation. In the case of biodiversity, the providers of the resources are frequently the biodiversity-rich countries of the Southern Hemisphere and at this time biological resources were considered a "common heritage" and, as such, subject to a free-flow paradigm. The primary international policy objective was the preservation of the common heritage: access to genetic resources was free, and the "guardians" of the resources were not rewarded (WIPO, 2001). From the early 1980s, some countries reacted to this inequitable situation by restricting access to the genetic resources under their jurisdiction (Glowka et al, 1994).

Two other "signposts" marked the changing way of thinking:

- In 1987, the World Commission on Environment and Development completed its report, which integrated conservation, economics and development in its famous formula for sustainable development.
- In 1991, the INBio-Merck bioprospecting contract was signed. The national Institute of Biodiversity (INBio) is a non-profit association whose objective is to integrate national biodiversity within society This agreement represented the first attempt to use biodiversity to achieve the commercialisation of genetic and biochemical resources.

As a result of these developments, efforts were made to achieve a broad and comprehensive approach during the deliberations leading up to the creation of the CBD. The negotiations often came close to breaking down. Nevertheless, the convention was concluded and – rightly – hailed as a landmark from several points of view.

In our context, the following basic decisions or elements of the CBD are significant:

- Biodiversity is comprehensively addressed: the scope of the convention encompasses both wild and domesticated biological diversity at genetic, species, and ecosystem level (Article 2, paragraph 1).
- It confirms the sovereign rights of states over their natural resources, i.e. the right of the

states to decide on the utilisation of their resources (Article 3). However, this right is not unlimited as: 1) states are responsible for conserving their own biodiversity and for using it in a sustainable manner (Article 6) and 2) states are obliged to facilitate access to genetic resources for environmentally sound uses by other contracting parties (Article 15 (2)).

- The regulation of access to genetic resources and the sharing of the benefits resulting from their utilisation integrates commercial, economic and trade dimensions.

Accordingly, the goals of the CBD are defined as "conservation of biodiversity, the sustainable use of its components, and the fair and equitable sharing of the benefits arising out of the utilisation of genetic resources" (Article 1).

Specific Issues

Prior to embarking on a discussion of the questions raised above it is important to take note of two basic points: firstly, the sovereignty of the state over its biological resources implies that the "primary/basic" property right belongs to the state, and it is within the state's discretion to decide whether and how this right is organised within its territory. Secondly, it is crucial to note that (as a rule), international agreements create rights and duties between the states as contracting parties only. The states are obliged to implement the contracts by taking national "legislative, administrative or policy measures" (the formulation in the CBD is frequently mitigated by the addition of "as far as possible and appropriate"). This fact is particularly relevant in cases like the BioLead project, in which a community negotiated directly with a company and no regulation existed at national level.

The regulation of access and benefit sharing (ABS)

According to the CBD (Article 15), the authority to determine access to genetic resources rests with the national governments and is subject to national legislation. However, certain conditions are also defined in the CBD: access must be on terms mutually agreed between the party providing the genetic resources and a potential user, and is subject to the prior informed consent (PIC) of the party providing the genetic resources.

The formulation "mutually agreed terms" implies negotiation between the party granting access to genetic resources and the entity that wishes to use them. The respective negotiations (can) result in an "access/ research agreement", which authorises and defines the conditions for access to genetic resources, controls subsequent use and establishes the return of the benefits. (Glowka 1998). Prior informed consent means that the consent by the competent entity is to be based on information provided by the potential user, such as how the resources will be used, and identifying the benefits sought.

The benefit-sharing regulation obliges the contracting parties "to take legislative, administrative or policy measures" whose aim is to share "in a fair and equitable way" the benefits arising from the utilisation of the resources provided (Article 15.7 CBD). The rationale behind this benefit-sharing provision is basically to reach a more equitable arrangement between the party providing the genetic resources and the party that uses them (Glowka, 1998). The benefits can be direct, such as monetary remuneration for access granted and samples provided, or indirect. The convention itself lists some examples for indirect compensation, such as provision for participation in scientific research (15.6), the sharing of research and development results and commercial and other benefits derived from genetic resource use (15.7), access to and transfer of technology for making use of genetic resources (16.3) and participation in biotechnological research activities based on genetic resources (19.1).

In our context, it is important to note that: 1) the authority to determine access and benefit sharing is located at national level and 2) none of the provisions on benefit sharing require *actual* benefit-sharing, but oblige the contracting parties *to take measures* whose aim is to share the benefits arising from the utilisation of the resources provided.
Thus, two conclusions can be drawn here: firstly, the CBD regulation involves a contractual solution to the question of access and benefit-sharing and does not define property rights to the immaterial value of genetic information or traditional knowledge; and, secondly, the implementation of prior informed consent and mutually agreed terms within the state rests with the national government. One problem with the convention becomes apparent here: on the purchaser's side, benefit sharing of genetic resources involves the private sector which – as a rule – cannot be obligated by an international convention; on the providers' side, social entities beyond state level can also be involved.[13] The question remains whether this structure makes sense from the incentive point of view, or whether it would not be more advantageous if entities at the lower level, which are directly concerned with the management of the resources, are integrated into the benefit sharing concept.[14] Up to now, the purchasers have had no control of the legitimate acquisition of genetic information.[15]

The integration of indigenous peoples and local communities by the CBD
The next question concerns the way in which indigenous peoples and local communities are taken into account in the CBD. Article 8 (j) considers indigenous and local communities[16] in the context of the value that their traditional knowledge, innovation and practices have for the conservation and sustainable use of biological diversity.[17] Contracting parties are urged to respect this traditional knowledge and to promote its wider application with the approval and involvement of its holders, and to encourage the equitable sharing of benefits. This formulation is similar to the PIC and benefit sharing formulae.
Furthermore, the contracting parties shall ("as far as possible and as appropriate") protect and encourage customary use of biological resources in accordance with traditional cultural practices that are compatible with conservation or sustainable use requirements. (CBD 10 c).
Taking account of the cultural embeddedness of traditional knowledge and customary use of biological resources, the implementation of this article is certainly broader than the implementation of the access and benefit sharing regulation alone. (Glowka, 1998). However, the integration of the traditional communities, in particular in view of the ABS regulation, depends entirely on the national legislation.
Thus, from the legal point of view, the following examination of the BioLead process and stakeholders will identify the elements leading to the success of the project and give an account of: 1) the regulation at national level concerning the state-communities relationship; 2) the process of the negotiating of the contract; 3) the provisions of the contract.

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13 In the (prototypic) InBio-Merck case, however, this was not the case. The bioprospecting activities were limited to the national conservation areas.

14 Cf. footnote XXX above

15 Discussions are underway on the inclusion of a declaration of legitimate access in accordance with the CBD, and including PIC and benefit sharing, in patenting procedures. However, to our knowledge, no such regulation has been enacted up to now.

16 Exact wording: "indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity"

17 In contrast to the IT which explicitly "recognize[s] the enormous contribution that the local and indigenous communities and farmers ... have made and will continue to make for the conservation and development of plant genetic resources which constitute the basis of food and agriculture production throughout the world".

2. The Novartis-UZACHI BioLead project

Overview

The Novartis-UZACHI BioLead (bio-prospecting) agreement, the first of this kind for Novartis, was set up in 1995: the actual collaboration and transfer of know-how, equipment and material took place between 1996 and 1998. The aim of this case study is to analyze the process and conditions leading to this collaboration, with a particular focus on the terms of access and benefit-sharing specified in the contract, and to answer the question as to whether and under which conditions bio-prospecting can create an incentive for inducing or fostering the conservation of biodiversity.
The basic objective of the collaboration was to evaluate and prove a scientific concept for the perturbation and the production of secondary metabolites in micro-organisms, and to explore the possibilities of direct collaboration between a pharmaceutical giant like Novartis and communities in a remote area of Oaxaca, Mexico.

2.1. Description of the context

Physical Environment
The project was carried out in the northern mountain range of Oaxaca which is composed of various ecological zones and a great variety in biodiversity. The area was chosen by Novarits because of its high diversity in fungi species, which is, in turn, associated with the high diversity in pine species. The State of Oaxaca, in southern Mexico (see Figure 2), covers an area of 9,536,400 hectares, which corresponds to 4.8% of the national territory. It has approximately 5.1 million hectares of forest, which represent 53% of Oaxaca's territory and 9% of Mexico's forests.[18] Oaxaca is characterized by its complex physical, geographical and ecological environment. The climate is predominantly (65% of the state's area) sub-humid (warm, semi-warm, temperate) with precipitation in summer, while a small part (13%) of the areas has a warm humid climate with a high precipitation. The rest (22%) of the state enjoys quite a dry climate (Arias 2000:1). Forest are important for the region's economic situation as its communities are dependent on timber production.

Property Rights
Public, private and common property exist in Mexico. In accordance with the agricultural legislation, all men above the age of 18 have the right to participate in the community assemblies. Within the *ejidal* system[19] , a second form of common property exists whereby only a fixed number of persons have the right to participate in the assemblies. For this reason, *ejidos* are generally more conservative, as the owners of these rights tend to be older.
The indigenous communities of Oaxaca own more than 90% of the state's forests. This creates interesting perspectives for the management of natural resources. For the most part, traditional forms of organisation are maintained here involving collective participation in the use of the resources and existing relationships of confidence and reciprocity. The productive systems are mostly a mix of external techniques and communitarian practices (SEMARNAP 2000(a): 172).

[18] OECD (1996:196): "Mexico is a Federal Republic of thirty-one sovereign states and one Federal District. The country is divided into 2407 municipalities and delegations […]. Environmental and conservation policy is characterized by a nested and complex array of legislation and authorities involving municipal, state and federal jurisdictions."
[19]

National Legislation[20]

*There is no specific law or regulation in Mexico that governs the problems of access and the sharing of the benefits generated by the use of genetic resources. An "Initiative for a Law to regulate Access to and Use of Biological and Genetic Resources" was launched by the Senate on 26 April 2001. Futhermore, "The General Law on Ecological Equilibrium and Environmental Protection" (*Ley General de Equilibrio Ecológico y Protección al Ambiente – LGEEPA*)*[21] was revised in 1996 and addresses the use and handling of biodiversity and genetic resources in the chapter "Wild Flora and Fauna" (*Título Tercero*) and provides some basic terms concerning ABS issues.[22]

2.2. Process leading to the establishment of the biolead agreement (actors, storyline)

2.2.1. Main actors

Unión de Comunidades Productoras Forestales Zapotecas-Chinantecas (UZACHI)[23]

Between 1956 and 1981 the forests of the northern mountain range in Oaxaca were exploited and heavily deforested by a paper industry concession. Following a difficult struggle between various communities and the paper industry, a judge ruled in favour of the communities and gave them back the right to use the forests properly. On September 14th, 1989, the communities of La Trinidad, Capulalpam de Mendez y Santiago Xiacui, populated by the Zapoteca ethnic group, and Santiago Comaltepec, populated by the Chinantecan ethnic group, were awarded legal status as the *Unión de Comunidades Productoras Forestales Zapotecas-Chinantecas* (UZACHI). The group consists of 950 community members, and the union has control over 26, 000 hectares of land, of which 88% is under forest cover.

From the perspective of UZACHI, one of the principal aims of the biolead project was that, in accordance with the CBD, the benefits accruing from a bio-prospecting agreement could be shared on the basis of a new type of relationship, i.e. the community-industrial partnerships (Novartis 1999:9).

The principal aims of the project for the UZACHI communities were:

- to support community autonomy and self sufficiency;
- to maintain cultural values;
- to seek to internalise the environmental costs of natural resource use;
- to develop specific projects which aim to maintain biodiversity.[24]

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[20] See www.mexico.gob.mx, www.ine.gob.mx, www.conabio.gob.mx and www.semarnat.gob.mx under "normatividad"; Spanish to English translation by the author.

[21] Material taken from http://www.semarnat.gob.mx/legislacion_ambiental/index.shtml/.

[22] Article 87bis:

The exploitation of species of the wild flora and fauna, as well as other biological resources with the aim to be used in biotechnology, requires the authorisation of the Secretariat.

The authorisation, referred to in this article, will only be given if the prior informed and expressed consent is obtained from the legitimate owner of the property where the biological resources are found.

Also such legitimate owners have the right to an equitable sharing of the benefits, now or in the future, being derived from the exploitation referred in this article, adapting to applicable jurisdictional dispositions.

[23] This material is based on Ramírez (1999) and Chapela, F. (1999 (b)).

[24] By generating the know-how to set up their own prospecting projects.

The goal was to reinforce the appropriation of the community resources, establish a non-extractive use of the protected areas and to search for possibilities for generating and diversifying their product range and income. Novartis supported this project by providing environmental education and technical training on biodiversity assessment (Novartis 1999:10).

External consultancy: Estudios Rurales y Asesoría, A.C. (ERA) – Rural Studies and Peasant Consultancy[25]

ERA is a non-profit civil organisation that was established by professionals who are concerned about the sustainable management of Mexico's natural resources and committed to making such a management approach a basis for providing social equity for development opportunities.

Members of the ERA are active on three levels in Mexican rural areas: (a) in research focusing on agriculture and forestry management systems; (b) in community work for fostering the saving and systematisation of their know-how and converting it into collectively sustainable development projects and (c) in collaboration with similar communities, as well as other civil and governmental organizations.[26]

Members of the ERA have been working in the Sierra Norte de Oaxaca and supporting the communities in this region since 1982.[27] They have helped the communities to design their community structures and establish sustainable management of their resources, specifically in terms of the establishment of a timber industry and development of a range of alternative products.

Novartis[28]

Novartis was created as the result of a merger between the chemicals and agrochemical concerns Ciba and Sandoz and is developing into what is described as a "life science" company. This concept was developed by Novartis to denote a more interdisciplinary approach linking different elements of biology, physics and chemistry with more specialised areas, such as pharmaceuticals, the agrochemical business and consumer health, with the aim of developing new and improved business opportunities. (Novartis 1999:4).

The main actor and Project Manager at Novartis was Dr Michael Dreyfuss. He worked at Sandoz/ Novartis from 1976 until 1998. Following some collection expeditions in the 1970s and 1980s, mainly to South America, he began to think about possible collaboration projects in the early 1980s. He was the initiator of the BioLead project; he started to work on its design in the early 1990s and it was approved after some years of internal negotiations.

Novartis Pharma (Sandoz) regarded the project as an ecological approach with the following main goals:

- to evaluate or prove a scientific concept;
- to maintain a project in a way that fully complies with the requirements of the CBD;
- to ensure the supply of microbial strains for lead findings.

The BioLead project was designed to reveal possible correlations between chemical diversity, the creativity of micro-organisms and ecological factors, as well as to develop a more

[25] Or according to Chapela (1999(a): 457): Rural Studies and Farm Consultancy.
[26] www.mesoamerica.org.mx/era.
[27] Chapela, F. (1999(b): 64): founded by twelve professionals.

[28] This project was initiated by Sandoz. The new pharmaceutical giant Novartis was created in 1996 with the merger of Ciba and Sandoz. For the purposes of this study, the PI will be referred to as Sandoz up to 1996 and Novartis from then on. See www.novartis.com.

structured approach in bio-prospecting in compliance with the CBD requirements. The company aimed to establish a more open and collaborative company strategy, including the exchange and sharing of technology and knowledge as a way of increasing the benefits arising from bio-prospecting for all partners involved (Novartis 2000:6).

Dr Ignacio Chapela

Dr Igancio Chapela was an important actor from the perspective of both ERA and UZACHI. He is a microbiologist, Assistant-Professor at the University of Berkeley,[29] scientific research director of the UZACHI, and brother of Francisco Chapela, who was one of the founders of ERA. Ignacio Chapela got involved when ERA started to look for possibilities for the communities to generate additional income. Having completed his PhD in England in 1987, he went to Basle to complete his post-doctoral qualifications where he met Dr Michael Dreyfuss (Project Manager BioLead). Thus, Dr Chapela was known and trusted by both parties.[30] In addition to his scientific knowledge, the experience he gained through his participation in the INBio-Merck negotiations in the early 1990s proved invaluable.[31]

2.2.2 Process leading to the establishment of the agreement[32]

The process leading to the establishment of the Biolead agreement can be divided into six phases.

Historical background

The initial mission of the communities in the Sierra Norte de Oaxaca, which later joined forces in UZACHI, was the fight against the FAPATUX (*Fábricas de Papel Tuxtepec)* to regain control over the community forests. The old agrarian law recognized the rights of the indigenous communities over their land and forests. Up to the 1950s, the communities basically practised domestic forest exploitation. The timber was used to build houses, to produce carbon and as fuel. The forest law was reformed in 1947 and the new law allowed the government to issue concessions by presidential decree to private companies for timber exploitation (SEMARNAP 2000(a):17). Besides some infrastructural support, i.e. the construction of some roads, members of the community could work for FAPATUX as non-specialised labourers for a small salary. In the ensuing period, large parts of the forests deteriorated or were completely destroyed due to the unsustainable logging methods used.

In 1979, a number of communities joined forces to establish the "Organization for the Defence of Natural Resources and Social Development in the Sierra Juárez"[33] with the aim of

[29] See www.cnr.berkeley.edu/chaplalab/ignacio.htm.

[30] He knew both partners "personally" and was qualified to quantify the benefits that could possibly accrue to them.

[31] InBio is a Costa Rican non-governmental, non-profit-making, scientific research institute whose orientation is social and based on the common good. It was established in October 1989. Merck is a research-driven multinational pharmaceutical and services company organized under the laws of the State of New Jersey, USA. The agreement, one of the very first bio-prospecting agreements was signed on 1 November 1991. For more detail cf.: Sittenfeld and Gámez (1993:69-97).

[32] See SEMARNAP (2000(a)), http://www.laneta.apc.org/rock/uzachi/uzachi2.htm and http://www.mesoamerica.org.mx/uzachi/UZACHI.html.

[33] ODRENASIJ – *Organización en Defensa de los Recursos Naturales y Desarollo Social de la Sierra Juárez*.

initiating the process for the legal revocation of the concessions (2000(a):18). After a difficult struggle, in 1982, a judge ruled in favour of the aforementioned organization (ODRENASIJ) giving the communities back their right to manage their forests.
In the late 1970s, future members of ERA started to work with the communities in the Sierra Norte de Oaxaca. They mainly provided technical support so that the communities could form teams, train technicians and thus systematise their experience and establish a sustainable community timber industry in the region (Chapela, F. 1999(a):457-458). This was the beginning of a long and deep relationship of shared visions, trust and mutual respect. To the present day, ERA remains the only consultancy used by UZACHI. ERA helped UZACHI to become one of the few agricultural organizations in Mexico with a structured mechanism for environmental management.

Appropriation of resources 1986-1992

Once the the forest had been re-appropriated, the aim was to find an appropriate means of managing the resources. When the communities embarked on using the forest in the mid-1980s, a new battle began. At the time, the Secretariat for Agriculture and Water Resources (*Secretaría de Agricultura y Recursos Hidráulicos – SARH*) was classifying and distributing the country's main forest areas in units of conservation and forest development (*Unidades de Conservación y Desarollo Forestal – UCODEFO*).[34] Forest professionals were employed for each of these units to provide technical services for forest exploitation. This support was mostly inadequate and rarely implemented, as the scheme had closer relationship with the timber industry than the communities. It was against this background that between 1985 and 1995 various communities decided to organize and form associations so that SARH would issue the concessions for technical forest services (TFS) in their favour. Thus, various community organizations emerged that organized around the TFS, and for which they finally received the relevant concessions (SEMARNAP 2000:19).

Designing the Biolead Project 1992-1994

In the early 1990s, the Communitarian Land Management Plan (*Plan Comunitario del Manejo del Territorio – PCMT*) was set up by technicians and approved by the communities. 40% of the UZACHI areas were defined as agro-forest land for agricultural purposes, 30% for commercial forestry, fuel for personal use and timber to sell or process in sawmills and joineries. With regard to the remaining 30%, the question emerged as to how the resources in the protected areas could be used in a manner that did not involve extraction. It seemed important to establish activities in these areas so as to make their presence evident. In the absence of such presence, neighbours could believe the areas in question to be available for colonisation and other uses.[35]
This territorial ordering of the resources of the entire area with the participation of all of the communities and the external consultant was a basic instrument for the development of all further projects. The PCMT tries to satisfy the necessities of the local population without destroying the environment. It was the basis for all existing forestry exploitation (involving both timber and non-timber products), used in all the implemented management programmes, and for all the different areas (Ramírez (1999:3) and Chapela, F. (1999(b):36-46)).
As UZACHI's consultant, ERA suggested that bio-prospecting agreements could have a certain potential for the generation of funds and knowledge that could be useful for further

[34] SEMARNAP (2000(a):22). The forest law was revised in 1986 allowing concessions for Technical Forest Services (TFS) to be issued to forest engineers.
[35] The idea that forests are unproductive and have to be converted into agricultural land remains a very strong legacy of the Agricultural Revolution.

projects. UZACHI was interested as foreigners were repeatedly observed on their territory making collections without informing the communities.[36] Thus, ERA provided them with the necessary information and UZACHI started to think about the possible terms of such an agreement. At this stage, as a trustworthy, knowledgeable and experienced informant, Ignacio Chapela proved very helpful.[37]

Throughout this stage, ERA passed the information on to UZACHI and generated a basic understanding of the context. Its task in relation to the project was to translate and facilitate the negotiations. The translation was not merely a linguistic process, it also involved making the indigenous communities' concepts clear to Sandoz and conveying Sandoz's ideas and interest to the communities. It was necessary to use the appropriate cultural codes to reach a mutual understanding. The facilitation basically consisted in supporting the flow of information between UZACHI and Sandoz in Basle, Switzerland. The goal was to reach agreements about specific issues and ultimately establish a contract which could be accepted by both stakeholders.[38]

Based on its discussion of the information provided, UZACHI[40] reached the following conclusions: if they were to establish a bio-prospecting agreement, it would not involve either (a) plants or (b) traditional knowledge.[41] Furthermore, (c) they would not allow foreign scientists any access to their resources and (d) the generated benefit would have to be considered adequate by the common membership meeting (CMM). These benefits should basically be of a non-monetary kind, such as education or transfer of know-how and equipment, which should serve different long-term purposes.[42]

Having refused to undertake any more collection expeditions in 1980, Dreyfuss started to design the BioLead project in the early 1990s. The CBD emerged in 1992 and entered into force in 1993. Dreyfuss worked on a project proposal over the following years and tackled many internal hurdles. It quickly became obvious that the main resource would be micro-fungi as these are of special importance for the pharmaceutical industry During all this time, Dreyfuss remained in contact with Ignacio Chapela, discussing the ongoing events. Thus, the flow of information had already been initiated before the project was approved in Basle.[43]

Negotiations and signing of the contract – 1994-1995

The Novartis Research Advisory Board approved the BioLead project in May 1994. According to Dreyfuss, hundreds of letters had been sent to research institutions and other

[36] Luna (UZACHI), 8 December 2002 and Ramírez (UZACHI), 12 December 2002; both personal communications.

[37] According to Chapela (ERA, 28 November 2002, personal communication), Ignacio Chapela knew the possibilities, needs and limits of the PIs and gained valuable experiences through his participation in the InBio-Merck negotiations in Costa Rica. He had also observed the activities of Shaman Pharmaceuticals, a company founded in 1993 and specialising in the discovery of new drugs from ethnobotanical leads worldwide (Chapela, I. 1997:250). It suffered extensive losses and was forced to cease trading in 1999. Thus, the local communities, from whom the ethnobotanical information originated, did not receive any benefits and no incentives were created for the conservation of biological diversity in those areas.

[38] See http://www.mesoamerica.org.mx/uzachi/ .

[40] During the first stage, the Representatives' Assembly discussed the topic over two years (Chapela, F. 2000(a)).

[41] Ramírez (UZACHI), 12 December 2001, personal communication. Due to complications that had been experienced by neighbouring communities when trading in traditional knowledge, it was decided that traditional knowledge should be protected and used for internal community purposes only.

[42] Chapela (ERA), 30 November 2001, personal communication.

[43] Dreyfuss (ex-Novartis), 14 January 2002, personal communication.

organisations with a potential for collaboration.[44] Approximately 50 microbiologists and research institutions from tropical and subtropical countries around the world, including UZACHI represented by Ignacio Chapel, passed the first selection.[45] All the potential partners were examined for their fulfilment of certain criteria, the feasibility of their involvement, their interest and clear motivation to see the project through. Other important criteria included an existing level of know-how in microbiology and ecology, as well as suitable site locations and habitats. Many interesting possibilities, for example one in Brazil had to be rejected, because the potential partners insisted on royalties which Sandoz was not prepared to pay.[46]

In 1995, three partners were selected and agreed on. These were: (a) the Tropical Research Institute in Panama; (b) the University of Goa in India and, last but not least, (c) the Mycological Facility in Oaxaca, Mexico (Novartis 1999:7).[47]

The contracts were set up in spring 1995, together with a patent lawyer and Dreyfuss, who provided the scientific input. They were considered basic standard contracts.[48] According to the lawyer, who was responsible for the contracts on the Sandoz side, from then on it was up to I. Chapela and ERA to present to and discuss with UZACHI what M. Dreyfuss had negotiated with his company officials. They knew that it would not be possible to achieve better conditions. The contract set up by Novartis basically already contained the important conclusions that had emerged during earlier discussions within UZACHI. The results of these discussion were known to Dreyfuss and he considered and mentioned them when setting up the contract at Novartis.

According to Luna,[49] the discussions that took place after the contract had been presented to the CMM by the representatives of the communities lasted six months.[50] The representatives, who had already discussed the topic, presented their conclusions and suggestions to the assembly. Over the six months, each of the *comuneros* had the opportunity to become acquainted with and challenge the contract or its terms. This participatory process ensured that everyone had the possibility of stating their thoughts and raising any problems they foresaw. Thus, the subsequent decisions of the general assembly were representative of and supported by the communities, although the ultimate decision was taken, as usual, by the general assembly which implemented its own aims. Furthermore, certain conditions existed that favoured such straightforward discussion. The most important of these was, undoubtedly, that there was no pressure to sign the agreement as it was not going to fulfil any basic needs.[51] The communities' basic income was already secure with the timber business and this contract would merely represent some "icing on the cake".

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[44] Dreyfuss (ex-Novartis) 14 January 2002, personal communication. Letters had been sent to all of the countries except Africa, because no possible counterparts could be identified there in course of the first selection.

[45] He did not have any competence to take decisions for the communities, as he was merely the link to Novartis.

[46] Dreyfuss (Ex-Novartis), 14 January 2002, personal communication.

[47] Initially, Dreyfuss (Ex-Novartis, 14 January 2002, personal communication) considered establishing five agreements, which was not possible in the circumstances. Many interested partners, e.g. in Brazil, were insisting on royalties which he was not allowed to pay.

[48] Strub (Novartis), 11 January 2002, personal communication: the Panama contract was in both Spanish and English, the Indian one in English and the Mexican one in Spanish.

[49] Luna (UZACHI), 8 December 2001, personal communication. Now President of UZACHI, at this time he was merely a normal member of the community.

[50] According to Strub (Novartis, 11 January 2002, personal communication), Ignacio Chapela was the point of departure and arrival for all of the information going from Novartis to UZACHI and vice versa. The information flowed through the following channel starting at Novartis; Dreyfuss – I. Chapela – ERA – UZACHI.

[51] Chapela (ERA), 10 December 2001, personal communication.

Objetives:

1. To investigate the relationship between the perturbation and the production of secondary metabolites in micro-organisms,
2. To explore the possibilities of negotiating and of working directly on collaborative projects between communities, industry, academic institutions and NGOs.

UZACHI's conditions:

- The contract should not involve the communities giving access to Novartis investigators ; the union technicians should instead be facilitated in carrying out the field work themselves.
- Under no circumstances should the collaboration with the industry involve the trading of traditional indigenous knowledge.
- The terms of the collaboration would have to be adapted to the Mexican legislation in force at the moment of the signature, or that coming into force during the duration of the project: 1994-1998.
- Novartis would have to pay in advance the cost of installating and equipping of a laboratory which would remain property of the union after completion of the contract.
- Novartis would have to pay for the training of the union personnel.
- Novartis would have to pay an annual fee to the communities, plus a productivity quota
- In the event of the discovery of a compound of pharmaceutical interest, arising from the the Novartis-UZACHI collaboration, Novartis would make a payment of a suitable sum to the union to create a heritage fund, to be used for the maintainance of its own basic technical equipment (Gonzalez (2000:5) mentions an amount of between US$ 1-2 million per active compound found).

Novartis's conditions:

- Exclusive use of the information generated by the project for a term of two years.
- Receipt of at least 1 000 isolations annually.
- Confidentiality with respect to the payments made and the information evaluated by Novartis over the term of two years.

Conditions of both parties:

- The isolations would only be made for investigation purposes. Novartis could not demand patents or other rights of intellectual property to the living species that may be involved in the project. In any case, they could call to each other rights on the procedures derived from the Novartis-UZACHI collaboration, in agreement with the contribution of the partners
- UZACHI would keep a register and duplicates of all the materials collected as evidence demonstrating that Novartis was not discovering organisms, to which it could claim property rights.

(taken from: Chapela and Massieu 2001: 26)

After six months of discussions the CMM finally decided to agree on the contract and enter into collaboration with Novartis. The contract was sent back with few changes, revised in Basle and immediately returned to Mexico with a small delegation and signed in August 1995.

Collection, isolation and delivery of samples – 1996-1998

The collections in Oaxaca started in 1996. The first was carried out by Lopez and Pérez from the laboratory and the entire group of forest technicians (around eight persons), however this process proved inefficient, thus, Pérez made the subsequent collections on her own and was helped in the laboratory by two assistants.[52] Pérez's work involved the planning of the collections, the collections themselves, the isolation of the samples, their characterisation and their delivery to Basle. Copies were made at the time of the extraction the samples. The copies still exist in the laboratory.[53]

[52] Clara Villanueva and Amparo Martínez, both technicians worked at the laboratory from the beginning of the project in 1995.

[53] Pérez (UZACHI), 5 December 2001, personal communication.

Two major problems that arose in the first months of the extraction of the samples concerned cleanliness and the time management. According to Pérez, obtaining permission from the government for sending the samples to Switzerland also proved difficult.[54]
The quantity of samples sent to Switzerland varied between 6000 and 9000.[55] With the delivery of the last samples in 1998, UZACHI concluded its part of the agreement and the laboratory became its property. The contract was set up for three years with an option for its extension. However, Novartis was not interested in an extension because it had already received a considerable volume of high quality samples and given the limited capacities within the natural compound unit, it would take a considerable time to process them. To the present day, the material generated by the BioLead project has not yet been fully analysed.[56]
Under the terms of the contract, Novartis is still obliged to inform UZACHI if an active compound is found within the collected samples.[57] In this event, a "success-fee" would have to be paid to allow UZACHI to create a heritage fund which would be adequate to support the work of the technical team indefinitely. According to Gonzalez (2000:4), the proposed sum is between US$ 1-2 million for each active compound (see Table 13). If a development period of ten to twelve years is assumed for the products, news of such a discovery cannot be expected until the year 2010 at the earliest.
Basically, UZACHI is interested in establishing other agreements and selling the generated material to other PIs. However, they will not do this as long as no legal framework exists with regard to ABS issues.[58] However, the experience gained in the BioLead project was very important for the communities. The gained a lot of confidence in their negotiating capacities and their traditional systems of access to "their" natural resources.
At the end of the collaboration, UZACHI received the laboratory, had established a team of technicians, a herbarium and sufficient funds to operate for one more year. The revolving funds, established with the annual fee of the project, descapitalized because of administrative incapacity and got lost in all the communities, with the exception of Trinidad (Chapela and Massieu 2001:25)

Confrontation, production of fungi and research from 1999

Finally, it is interesting to see how the know-how and the technology acquired after the completion of the contract were used to develop other products and generate additional income. One of UZACHI's projects is a biodiversity program which aims to: (a) generate know-how and technological skills for the use of saprophytic fungi originating in the communities; (b) generate alternatives for the standard income based on non-timber activities; (c) increase the economic value of the forest areas of UZACHI by producing forestry by-products. The mycelia of these fungi are processed in the union's laboratory. The fungi are promoted by project technicians (Ramírez 1999:6). [59] This project basically aims to improve the appropriation and use of the communities' natural resources.

Another of the union laboratory's initiatives involves research into the contamination of maize landraces in the Oaxaca region with genetically engineered varieties.

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[54] According to Pérez (UZACHI, 5 December 2001, personal communication), she had to ask the office for wildlife, INE, for permission to export the samples. The LGEEPA had not yet been revised.
[55] Ribeiro (RAFI, 13 December 2001, personal communication) said that she was told so by Lilia Pérez.
[56] Strub (Novartis), 11 January 2002, personal communication.
[57] ibid.
[58] Luna (UZACHI), 8 December 2001, personal communication.
[59] Ramírez (1999:5). The main UZACHI projects are to: (a) improve timber exploitation, (b) improve the genetic characteristics of pine species, (c) improve the agricultural systems and (d) learn about non-timber species, such as fungi and orchids, and their potential uses.

In Nature 414 (2001), Chapelas and Quist reported that they had found transgenic DNA from genetically modified maize in local varieties of the crop in Oaxaca[60] in spite of the fact that in 1998 Mexico prohibited the import of genetically modified crops (GMC) as seed-material. However, transgenic corn is widely sold for consumption in Mexico (Dalton, 2001). Chapelas and Quist conclude that their results demonstrate that "there is a high level of gene flow from industrially produced maize towards populations of progenitor landraces" They judge the result as particularly striking given the moratorium. Whether the presence of these transgenes in 2000 followed by the survival of transgenes in the population, remains to be established." The publication of these findings prompted vehement discussions.[61]

Pérez carried out the first analysis in the UZACHI laboratory having acquired the know-how and the relevant instruments to implement further DNA screening and analysis. Thus, the laboratory team continues to work, improve and use its know-how for further projects.

Dr Alejandro Nadal wrote an article in *La Jornada* about the UNAM- case in October 1999, stating that their contract contradicts the LGEEPA and is, thus, illegal. In July 2000, he placed a popular denouncement at Profepa against this contract. Sensitive to "indigenous problems" as a result of the former *Marcha Zapatista*, in which/where their rights had been discussed, the public supported the topic, producing a wave of disagreement.[62] The disagreement grew, encompassing all ongoing and recent projects and initially no distinction was made between them.

This marked the beginning of a rather dark chapter in the BioLead project when the accusations against UZACHI and ERA went further than being a controversial topic for discussion. Gonzalez (2000:4) accuses UZACHI of selling organisms that could also be found in neighbouring communities who did not receive any of the benefits agreed with Sandoz . He says that this happened as a result of a failure in communication and the fact that the communities were not informed. He also accused ERA trying to benefit from the agreement.[63] Ribeiro even went further, saying that it is one of the worst contracts ever to exist. She says that diversity is a public good and not private property and should not, therefore, be sold.[64]

The good "personal" relationship between the partners, the personal efforts made to establish the arrangement, the optimal flow of information, the strict organization of the union with regard to the use of their resources, their remarkable social capital and other specific circumstances all contributed to the successful conclusion of this project. Novartis even sees this form of "meta-organisation" as indispensable to the realisation of the project (Novartis 1999:10)

2.3. Access and benefit sharing (ABS) and the definition of rights

The case examined here is very special and exhibits some unique attributes. From the stakeholders (see previous section) and property rights to the PIC and the benefits derived by

[60] According to Dalton (2001), Oaxaca is the global centre of corn diversity and the place of origin of strains grown commercially around the world
[61] Cf. Nature 415, 416,
[62] De Ita (Ceccam), 12 December 2001 and Colín (Greenpeace), 13 December 2001; both personal communications.
[63] Ramírez (UZACHI), 1 December 2001, personal communication.
[64] Ribeiro (RAFI), 13 December 2001, personal communication.

the stakeholders, all of the elements of this case work together to achieve the three goals of the CBD, which are the conservation of biological resources, their sustainable use and the equitable sharing of the benefits arising from their use.

Property rights of the local communities

As described above, according to Article 3 of the CBD the state has the sovereign right to exploit its own resources. The inclusion of local communities into the ABS procedures thus depends on the national legislation and the definition of the ownership of the resources is crucial.

In this context it is important to be aware of the dual nature of genetic resources: they are both physical material and the carriers of hereditary information (which is, moreover, *capable of self-replication*). This dual nature gives rise to a conceptual tension between physical property, on the one hand, and property rights to the intangible elements of genetic resources, on the other (WIPO, 2001). The genetic information is a value in itself: its ownership can be regulated independently of the ownership of the physical organism in which it is contained. Thus, in principle, there are two possible points of connection for the regulation of authority to grant access: 1) it can be given to the holder of the physical resource (ownership or usufruct), or 2) to the owner of the informational value.

According to Glowka (1998), without specific supplementary legislation which clarifies the legal status of genetic resources, the legal status of the material in which they are found would normally apply, and the legal status of micro-organisms growing in in-situ conditions would appear to be tied to the territory where they are collected. This would be the case in the Oaxaca example; the provisions of the Mexican constitution support this solution. The right of the communities to exploit their forests was one of the crucial elements for the success of the BioLead project.

It becomes apparent that in taking the right to the territory as a point of connection, the issue is closely linked to the thorny question of land rights and this is, moreover, further complicated by the fact that the communities living in areas rich in biodiversity are frequently marginalised minorities. In Mexico, the rights of the communities to their land and its products has a historical (if not unchallenged) tradition, and the subsequent amendment of the LGEEPA seems to point to a similar solution.

However, another possible line of argument is that, as long as no specific regulations exist, the state is the owner of the genetic information. This perspective is supported by certain emerging trends, for example, Decision 391 of the Andean Community on the "Common Regime on Access to Genetic Resources" declares genetic resources as being "national patrimony" and identifies the property rights to these resources as remaining with the state, regardless of the property rights regime applicable to the biological resources which contain the genetic information, the land in which they are found or the associated knowledge. The same was true of the Costa Rican legislation at the time of the INBio-Merck contract. The argumentation used by the representative of RAFI (now ETC-group), stating that diversity is a public good which cannot be sold, also points to this interpretation.

Property rights to the resources isolated from the original resource (such as secondary metabolites) are not regulated in Mexico.

According to the BioLead contract, UZACHI retains the right of ownership to the (isolated and characterised) strains delivered to Basle, while Novartis has the right to apply for patents derived from innovations achieved in the course of the study and consisting of or containing any compounds derived from these resources (see Table 3). The agreement excluded intellectual property rights over the (isolated?) species involved in the project.

Prior Informed Consent (PIC)

According to the CBD, the providers of genetic resources must be informed about the potential of the resources, their future use and how they will be compensated for their use.

Thus, if local communities are involved in the access and benefit-sharing negotiations, the holder/owner of the information must be identified. Different options are possible: private vs public (community) ownership or, as it was the case in Oaxaca, shared ownership by several communities. If several persons or entities are involved, the persons authorised to represent the community in negotiations must be defined and procedures established for the decision-making process.

Furthermore, negotiations are complicated by the fact that they take place at the interface between different research and business cultures. Thus, the providers must engage in processes of organisation and joint management of the resources and they must also build their capacities in terms of the negotiation process.

The structure and organisation of UZACHI enabled all the participants, i.e. the members of the communities, to be kept informed through the regular assemblies. Due to the fact that ERA, which was responsible for the exchange of information, is run by local people who had solid insight into the options open to the users of the resource (provided by I. Chapela) and had established an appropriate trustworthy link to the industry (M. Dreyfuss), problems regarding language and cultural barriers did not arise. The interviews carried out in the communities revealed that they were properly informed about the contract and its terms and had had ample opportunity to raise objections, discuss them and contribute their own ideas.[65]

Mutually Agreed Terms (MAT)

As a result of these negotiations, the contract between UZACHI and Sandoz, which was basically a Material Transfer Agreement (MTA), was signed in 1995. As far as can be assessed from the information available, it appears that both parties were able to formulate and introduce their specific conditions and that consensus was reached through a fair and transparent process. What is interesting in this context is the opinion-building process within UZACHI. Based on the discussion of the information provided and of experiences of other communities with bioprospecting, UZACHI[157] drew the following conclusions: if they were to establish a bioprospecting agreement, it would not involve either (a) plants or (b) traditional knowledge. Furthermore, (c) they would not grant any foreign scientists access to their resources and (d) the generated benefit would have to be considered adequate by the Community Membership Meeting (CMM). These benefits should be basically non-monetary in nature, such as education or transfer of know-how and equipment which would serve various long-term purposes.

Without having seen the actual contract, but having held detailed discussions with the persons involved, the authors believes that the contract fully observed the very general guidelines in the CBD with respect to ABS problems.

A range of benefits can be identified: (a) the transfer of technology and know how; (b) annual payments; (c) sample fees; (d) salaries for three persons working at the laboratory for four years and (e) a "success-fee" to be paid, if Novartis discovers active compounds among the samples delivered by UZACHI and develops a marketable product. A fixed payment was agreed on, in the knowledge that it would take years to develop such a product and that the chances of its success would be infinitesimal. Benefits from present activities are generated

[65] Ramírez (UZACHI), 1 December 2001, Luna (UZACHI), 8 December 2001 and Ruiz (UZACHI), 9 December 2001, personal communications.

through the processing of fungi mycelia and through the implementation of other investigations.

3. Lessons to be learnt and the transferability of experience

Unique case
(scientific and not commercial interest of PI, triggered by personal interest, organisational and administrative structure of UZACHI, personal relationship)

Lessons to be learnt
In summary, it is possible to identify the following elements as important for the success of an access and benefit-sharing agreement:

- Clarification of the legal status of the biological (microbial or genetic) resources.
- Designation of the actors entitled to make decisions regarding access to the resources.
- Where local communities are involved in the process, clarity within the community with respect to the assignation of rights, the procedures for decision-making and the representation in negotiation.
- Where local communities are involved, capacity building processes with respect to the internal organisation, negotiation skills, and understanding of different cultures.

In the case of the BioLead project, UZACHI's ownership of the forest resources and the structures and opinion-building processes established by the communities for the management of these resources strongly supported the successful conclusion and implementation of the agreement.

Abbreviations and Acronyms
CBD Convention on Biological Diversity
IT International Treaty on Plant Genetic Resources for Food and Agriculture
WIPO World Intellectual Property Organisation
PIC Prior informed consent
ABS Access and benefit sharing
LGEEPA Ley General de Equilibro Ecològico y Protecciòn al Ambiente

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