

**BIOETHIC AND THE CHALLENGES OF BRAZIL IN
CONFRONTATION WITH INTERNATIONAL LAW**

***BIOÉTICO E OS DESAFIOS DO BRASIL NA CONFRONTAÇÃO COM
LEI INTERNACIONAL***

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ABSTRACT

This paper investigates the regulation of bioprospecting in Brazil, examining especially the appropriateness of the legislation in relation to the principles of the Convention on Biological Diversity (CBD) and the Trade-Related Aspects of Intellectual Property Rights (TRIPS). It also discusses the situation that has been agreed in the covenants signed between Brazil and other countries, in view of preserving the diversity and integrity of the genetic patrimony of the country.

KEYWORDS: Bioprospecting; Biolaw; Contracts; Genetic Patrimony.

RESUMO

Este artigo investiga a regulamentação da bioprospecção no Brasil, examinando especialmente a adequação da legislação em relação aos princípios da Convenção sobre Diversidade Biológica (CBD) e dos Aspectos dos Direitos de Propriedade Intelectual Relacionados ao Comércio (TRIPS). Discute também a situação que foi acordada nos convênios assinados entre o Brasil e outros países, tendo em vista a preservação da diversidade e integridade do patrimônio genético do país.

PALAVRAS-CHAVE: Bioprospecção; Bio-Direito; Contratos; Patrimônio Genético

INTRODUCTION

The Federal Constitution of Brazil, when discoursing on art. 225, that all individuals have the right to an ecologically balanced environment, of common use, and essential to a healthy quality of life, imposes upon the Government and the community the duty to defend and preserve it. The first paragraph, section II and the fourth paragraph of the said article, set down that "it is for the Government to preserve the diversity and integrity of the genetic patrimony of the country and control entities engaged in research and manipulation of genetic material, including the use of natural resources."

Thus, Brazil signed on June 5, 1992 the Convention on Biological Diversity (CBD) adopted at the United Nations Conference on Environment and Development, held in June 1992 in the city of Rio de Janeiro and came into force internationally on December 29, 1993. This agreement was approved by the National Congress of Brazil through Legislative Decree No. 02 of February 31, 1994, ratified by Brazil on February 28, 1994 and entered the Brazilian legal system through the enactment of Decree No. 2,519 of March 16, 1998.

Provisional Measure No. 2,186-16 of August 23, 2001, aims to regulate the section II of paragraph 1 and paragraph 4 of article 225 of the Federal Constitution of Brazil, and article 1, article 8 letter "j", article 10 letter "c", articles 15 and 16 paragraphs 3 and 4 of the Convention on Biological Diversity, which provide for access to genetic

resources, protection and access to associated traditional knowledge, benefit sharing, as well as access to technology and technology transfer for its conservation and use. These genetic resources are having a significant and growing economic importance for the development of modern biotechnology with genetic engineering, a technique for gene manipulation, as one of its most important areas.

The above law regulates access to and shipment of samples of genetic components and its associated traditional knowledge by public or private entities engaged in activities of research and development in the biological and related fields.

Such bioprospecting creates a unique opportunity that both helps conserve biodiversity and preserve social diversity, and serves to promote the development of countries that own such resources in view of generating benefits for all parties involved.

With the most considerable diversity of animals and plants on the planet (between 15% and 20% of the total number of species), Brazil occupies a prominent role in the debate about the potential of bioprospecting. Some of the richest ecosystems in terms of number of species of plants - the Amazon, the Atlantic Forest, Pantanal and Cerrado - are located in this country. Brazil is also regarded as a country of substantial social diversity, with a very rich set of traditional populations, including indigenous peoples, ribeirinhos, caiçaras, seringueiros, among others. These groups of people are users of low-impact technology whose knowledge is often a key to accessing and exploiting biodiversity resources.

Beyond its natural wealth and social diversity, Brazil also enjoys other relevant advantages, such as a good scientific infrastructure, the availability of human resources, as well as universities and public research institutions with the potential to lead bioprospecting activities in the country. In addition, Brazil represents a large market for pharmaceuticals and is a major participant in world agricultural trade. All these features put the Brazilian position in relation to bioprospecting alongside that of other major global players such as the United States, European Union and Japan, which are the main countries represented in the Amazon region with strong interests in its biodiversity.

2 THE CONCEPT OF BIOPROSPECTING

Bioprospecting can be defined as the exploitation of biodiversity in view of extracting genetic and biochemical resources for economic and social value (BEATTIE, 2005). This process can make use of the knowledge of indigenous or traditional people (SANT'ANA, 2002) and relies on advanced technologies to develop new pharmaceuticals components, agrochemicals, cosmetics, fragrances, industrial enzymes, among others. (ARTUSO, 2002).

As observed by Reid et al. (1993), bioprospecting creates opportunities for the governments of countries rich in biodiversity to reap economic benefits from the exploitation of their natural wealth, whilst still conserving biodiversity. This would both promote the development of countries possessing such resources and generate attractive revenue for the industry.

Bioprospecting can be applied to various activities, impacting different sectors of the economy, especially in the fields of pharmaceuticals, cosmetology, food and agricultural inputs in general.

The legal principles that ensure bioprospecting as area of knowledge are: i) the precautionary principle - in doubt as to irreversible damage the activity should not be started or continued, ii) the principle of conservation of resources - resources should not be depleted, iii) the principle of distributive equity - the benefits should be shared between all parties involved in the activity, iv) the principle of public participation - ensuring wider participation of the people involved through public or private entities and even individual citizens, v) the principle of transparency - all acts of the activity should be transparent to the public, by treating the natural resources and sharing its benefits (PAVARINI, 2000).

The original principle to bioprospecting, that is hitherto accepted by most countries, has been that "genetic resources should be available for any and all purposes, as end products benefit all societies" (Caillaux & MÜLLER 1998 and Azevedo, 2003). However, with the growth of the biotechnology industry and its drive towards patenting processes or products developed from such resources, countries rich in genetic diversity began to change their attitude regarding the exploitation of these resources in order to control their access (Azevedo, 2003).

The late 1980s saw a paradigm shift regarding the sovereignty over genetic resources. In the early 1990s, the debate on the importance and value of biodiversity resurfaced, but this time with a focus on bioprospecting. Since then, the use of biodiversity resources has been based on a new paradigm. They include areas like information science and technology, and their applications in the production processes of companies (Lasmar, 2005).

To this end, the need arose for an international regime to promote the fair and equitable distribution of gains from biodiversity, while taking a systemic view on the allocation of these resources (Enriquez, 2005). The general consensus was to establish a new international treaty, rather than an 'umbrella convention' grouping all existing International Conventions on the subject together. The Convention on Biological Diversity (CBD) was held in 1992 in the city of Rio de Janeiro in order to form a more uniform understanding of the subject.

With the advent of CBD, new actors have entered into studies and discussions on the various manifestations of biodiversity. As a multidimensional activity (a collective practice conditioned by other social practices) involving actors as diverse as scientists and non-scientists, politicians, academics, industrialists, technologists, representatives of indigenous communities, the State, non-governmental organizations (NGOs) and various other interest groups, bioprospecting in the field of scientific and technological development reveals a myriad of relationships and disputes of all kinds (TRIGUEIRO 2006 and DAYS & COSTA, 2008). As noted by Polski (2005), the CBD marks the beginning of new relationships between actors using the resources and biodiversity conservation. In order to better understand the various groups active in the practice of bioprospecting, actors can be divided into the following three categories:

a) Creators of knowledge - actors who most often have prior knowledge of bioprospecting and the bioprospecting process. Academic and corporate scientists and communities of traditional knowledge such as quilombolas, riparian, fishermen who can generate new knowledge, products, processes or applications, or create profitable products;

b) Entrepreneurs – actors bioprospecting biological resources within or outside the country in which their enterprises are located (businessmen, farmers, vendors,

biotechnologists etc.), with the aim of developing new products, processes and profitable applications which can bring this knowledge forward;

c) Collectors - actors who harvest genetic samples to expand own collection or sell to others.

In view of the high complexity surrounding the practice of bioprospecting, as well as the high technological and economic risks that are associated with it, there is a need to establish very specific rules or institutions to enable development. Good regulation of bioprospecting is essential in order to ensure that it contributes both to the conservation of natural resources for economic development of the countries involved in the process, as well as to their social development through partnerships that lead to shared monetary and non-monetary benefits. In particular, government, non-governmental organizations (NGOs), public and private universities, chemical, pharmaceutical and other companies as well as communities should participate directly through agreements, concessions, permissions and partnerships in general, where the responsibilities for all parties involved are clearly defined.

Despite the growing practice of bioprospecting by the industry however, only a few developing countries have seized the opportunity and begun to exploit their natural resources properly. According to Silveira et al. (2004), within this select group of countries, Brazil has the preconditions to lead bioprospecting activities in the world because of its good scientific and technological infrastructure, the availability of human resources, as well as its many universities and public research institutions in life sciences.

3 TRIPS VERSUS CBD: CONFLICTS AND CONTROVERSIES ON THE WAY TO NATIONAL REGULATION

The CBD was created in order to define a sustainable development policy that regulates the use of biodiversity resources and the enhancement of traditional knowledge. With this purpose in mind, it includes principles for fair and equitable sharing of benefits arising from the use of these resources and recognizes the national sovereignty of States.

However, the implementation of these principles finds itself at odds with certain clauses of the TRIPS Agreement. This inherent tension between parts of the CBD and TRIPS has yet to be fully eliminated.

The discrepancies between the TRIPS and CBD agreements are related to their respectively different goals and interests. The signatories of both agreements aim to pursue a path where bioprospecting is practiced in such a way that it benefits all stakeholders without opposing the principles of either agreement.

According to Guerrante (2003), the main differences and conflicts between the TRIPS Agreement and the CBD are:

- CBD grants to States National the legal capacity to face "biosquatting" with prior information. In TRIPS, there is no provision requiring prior informed consent for access to biological resources that may later become protected by Intellectual Property Rights (IPR). Therefore, ignoring such a provision serves to encourage biosquatting;
- According to CBD, National States have sovereign rights over their biological resources. This assumes that sovereign countries have the right to prohibit or to authorize IPRs on living beings. In TRIPS, biological resources have to be subjected to private rights of intellectual property;
- CBD establishes a legal basis for developing countries to claim their share in the benefits arising from the utilization of biological resources and traditional knowledge. TRIPS, on the other hand, stipulates that it is necessary to grant patents in all fields of technology, therefore, the use and exploitation of biological resources are protected by IPRs. However, it provides no mechanism to ensure that benefits are shared between the patentee and the resource provider;
- CBD favors public interest and wellbeing over regards for private property, when it stipulates that signatory states are obliged to promote the conservation and sustainable use of biodiversity as a common concern for the rights of all humanity. In TRIPS, the protection of public health and food safety, as well as public interests in general, are subordinated to the private interests of the holders of IPRs.

These conflicts between the CBD and TRIPS originate in Article 27.3b of TRIPS, allowing intellectual property rights for microorganisms, non-biological and microbiological processes. Article 27.3 (b) authorizes member states to exclude, in their national legislation, the patenting of plants, animals and essentially biological

processes for the production of plants and animals, but obliges member states to protect patents for microorganisms, non-biological and microbiological processes as well as determines what varieties of plants to be protected by patents or by an effective *sui generis* system or by a combination of both. (DEL NERO, 1998).

Article 27.3 (b) of TRIPS conflicts with Article 8 (j) of the CBD, which states that each contracting party is obliged, in accordance with their national legislation, to:

Respect, preserve and maintain knowledge, innovations and practices of local communities and indigenous peoples with traditional style relevant to the conservation and sustainable use of biological diversity life and also promote their wider application with the approval and involvement of the holders of such knowledge, innovations and practices and encourage the equitable sharing of benefits arising from the utilization of such knowledge, innovations and practices "(CBD, 1992).

Therefore, the conflict is in the dispute that occurs between the aforementioned provisions of the two articles, "for there is an understanding among some countries that patents on genetic resources would not be compatible with national sovereignty and, thus, any patenting of life forms, including microorganisms should be prohibited " (ADAME *et al.*2008).

Passos (2006, p.330) states on Article 8 of CBD that: The phrase contained in the caput of Article 8, "as far as possible", as well as the words "promote" and "encouraging", expressed in paragraph j, seem to remove the obligation of the precept, allowing such provisions to not be implemented as it would be desirable for the preservation of elements of biological diversity.

Another point of contention regarding CBD concerns the transfer of technology. Within the CBD, access to genetic materials in developing countries by developed countries that are rich in technology and capital resources is conditioned on allowing access to resources by the former, and on the transfer of technologies for sustainable use of these resources, as well as the distribution of economic benefits by the latter.

According to Mascanheras (2004, p.406), the issue of access to technology has proven to be problematic on two fronts: first, many developed countries such as the U.S. are refusing to adhere to this condition of the agreement, and second, the

technological gap and the lack of human and financial resources to devote to these research efforts in most developing countries have hindered a wider adoption of the principles of CBD.

Another article of the Convention that causes controversy regarding the sovereignty of States over their natural resources is Article 22, first paragraph: "The provisions of this Convention shall not affect the rights and obligations of any Contracting Party deriving from any international agreement existing, unless the exercise of those rights and the fulfillment of these obligations cause serious injury or threat to biological diversity. " According to Passos (2006), this article "leaves open the possibility of other international agreements (which have not focused on the precautionary principle and, much less, environmental concerns) to have precedence over the CBD, for there is difficulties in scientific accuracies as to what in fact is considered potentially serious damage or threat to biological diversity. "

As Passos observes, the sovereignty of States over their national resources, recognized by the CBD, merely gives to states the right to negotiate them (under international trade rules), but do not exempt them from the rules of market and multilateral trading systems such as the World Trade Organization (WTO).

Nevertheless, Mascanheras (2004) suggests that developing countries can build strategies to defend their growth when threatened by the high standards set by TRIPS. Possible defense strategies are:

- Exploring legal ambiguities:

1. One of the strong limitations to meeting the high standards required in TRIPS is the rudimentary institutional infrastructure for the international intellectual property system and the need to coordinate with national systems, and only in some cases would the WTO infrastructure for dispute resolution would be able or available to equate these disputes;

2. The structure of the law itself contains broad provisions that are not adequately addressed or implemented even in the WTO, thus opening up for different interpretations, which favors non-compliance as intended, given the ambiguities;

- Counterbalancing regulatory measures: in developing countries there is firstly the need to attract foreign direct investment and, secondly, there is dependence on external technologies, which may lead these countries to overestimate market mechanisms and also the sheer competition to the prejudice of their similarity to the strict regulation of TRIPS;

- Safeguards Provisions: There are many blind spots for the coercive mechanisms by not adopting to the TRIPS, and strategies can stimulate the signatory countries, and especially the use of safeguards already provided in cases where application of the rule finds serious economic obstacles to their adoption, the law itself provides for adjustment periods, mainly in developing countries.

In this context, to adjust the provisions of TRIPS to the principles of CBD, the conflict between the principles of the agreements shall be resolved through international negotiations, because the national legal and regulatory framework is reflective landmark international legal and normative. Many countries, perhaps for lack of preparation, end up simply transcribing the rules of the agreements, while failing to make a rule that prioritizes the needs and interests of their countries.

Other countries, when trying to make rules for the use of and access to biodiversity and traditional knowledge resources, which both meet national interests and at the same time satisfy the principles of the agreements, eventually encounter unresolved tensions due to the differing stakes of various interest groups. For this reason, there is an urgent need to harmonize these agreements.

4 BRAZILIAN LEGISLATION ADOPTING PRINCIPLES OF THE TRIPS

As a WTO member, Brazil adopted to the principles of TRIPS until 2000, the country was committed to implementing the necessary changes required by TRIPS, with the signing of the "Final Minutes of Multilateral Trade Negotiations in the Uruguay Round", in April 15, 1994 in Marrakech. To this end, new laws were introduced bringing

about important changes for agricultural biodiversity, as well as farmers and local and indigenous communities.

In 1996, Law No. 9,279 (Industrial Property Law) was enacted to regulate intellectual property in Brazil, amended by Law no. 10,196 of February 14, 2001. On April 25, 1997, Law No. 9,456 (Plant Variety Protection Law - PVPL) was enacted, and regulated by Decree. 2,366, of November 5, 1997. (GERMAN-CASTELLI, 2004).

The Industrial Property Law in Brazil, adapting to the precepts of TRIPS determines which inventions are susceptible of being patented, excepting those arising from discoveries, extracts and active ingredients isolated from plants.

This means that the referenced legislation has determined that only pharmaceutical compositions containing extracts or active principles are patentable. The patenting of genetic material of animals and plants, such as genome and germplasm (except when differentiated from their state in nature) is prohibited, as it is considered as mere discovery, thus not fulfilling the requirement for patentability. (VIEIRA, BUAINAIN, SILVEIRA & VIEIRA JUNIOR, 2007).

In Brazil, the Industrial Property Law expresses the power of who holds technology as well as international agreements, because the monopoly of use of a patent is 20 years, and of the utility model is 15 years (GERMAN-CASTELLI, 2004).

With the entry into force of the Industrial Property Law, chemicals, medicines and food declared as inventions, as well as biotechnological processes resulting from new biotechnologies and transgenic microorganisms began to be patentable. However, Brazil does not "grant patent for natural living organisms, or parts thereof, even if isolated from nature, including its genome or germplasm." (GERMAN-CASTELLI, 2004).

According to Article 10, not considered an invention or utility model are: Item IX - all or part of natural living beings and biological materials found in nature or isolated therefrom, including the genome or germplasm of any natural living being and natural biological processes. Article 18 - not patentable are- all or part of living beings, except transgenic microorganisms meeting the three patentability requirements, which are not mere discoveries; Sole paragraph - For the purposes of this Act, transgenic microorganisms are organisms except all or part of plants or animals That express a

characteristic due to direct human intervention in their genetic composition that can not normally be achieved by the species.

Regarding the Plant Variety Protection Act (Law No. 9.456/97), in the words of German-Castelli argues that the passage of this law was imperative to Brazil's adherence to UPOV (International Union for the Protection of New Varieties of Plants Council). The Final Act of the Uruguay Round of GATT, approved by the Brazilian Congress through Decree 1355, provided in the TRIP (Agreement on Trade-Related Aspects of Intellectual Property including Real Fake) the adoption of sui generis systems for the protection of plant varieties by signatory countries (Art.27.3.b).

This engagement did not involve the obligatory adherence to UPOV by Brazil. As a sui generis system does not necessarily coincide with the standards imposed by legislation of such entity. At the time, some nationalist sectors of the Brazilian scientific community recommend the franchise system (franchising) as the most appropriate profile for the Brazilian sui generis legislation. At the moment of decision, however, dominated the government's position that pointed the diplomatic isolation of the country, if not adhered to UPOV.

For the Plant Variety Protection Act, the object of protection supervised by the right of the breeder is the cultivar (variety of any plant genus or species exceeding that is clearly distinguishable from other cultivars), known by a minimum margin of descriptors for your own denomination is homogeneous and stable - art. 3rd. LPC - (VIEIRA, BUAINAIN, VIEIRA JUNIOR & Silveira, 2007).

In Brazil, the National Institute of Industrial Property (INPI) is a federal agency responsible for granting the registration of industrial property rights in the country. Among its responsibilities is the registration of technology transfer and nationwide business franchise contracts. In addition, INPI arbitrates the allocation of Conventions, Treaties and Agreements that deal with industrial property, and participates in debates and international negotiations.

Applications for the registration of industrial property in Brazil must be filed with the INPI, with a detailed description of what to be registered among other specific requirements. Outside the country, the procedure may also be done through the INPI, which will make contact with other Industrial Property Offices and proceed with the application for registration under international law.

Before filing a patent with the INPI for e.g. a modified molecule, or a process of synthesis making use of biodiversity resources and traditional knowledge, several steps should first have been completed, namely: i) institutional accreditation by the Board of Management of Genetic Patrimony (CGEN) to access and value (special license for collection and transportation of the material), ii) access authorization by the land owner or knowledge - informed consent; iii) if inflow forecast on Native Indian land it is necessary to request specific authorization from the National Indian Foundation - FUNAI, including obtaining the prior informed consent (pre-requisite to obtaining authorization from CGEN) of the indigenous community is possible, and, iv) Provision of Service contract in equity genetic and benefit sharing - registered in CGEN.

According to Resolution no. 23/2006 of CGEN, the applicant of a patent product or process resulting from access to genetic heritage components must declare fulfill the conditions of Provisional Measure no. 2.186-16/01 and report the number and date of the corresponding access authorization, issued by CGEN. Resolution no. 134/2006 of the INPI, in turn, explains this procedure, requiring the applicant to inform the INPI whether or not the request object has been obtained through access to the national genetic heritage (MATHIAS, 2008).

5 THE BRAZILIAN LEGISLATION ON BIOLOGICAL DIVERSITY COMPLYING WITH PRINCIPLES OF CBD

Brazil was one of the first signatories of the Convention on Biological Diversity. Brazil has actively participated in international negotiations and has been present in several international forums dealing with this issue. To meet the requirements of the CBD, changes in legislation have been implemented, such as Act No. 2186-16 of 2001 and Decree No. 3.945 Measure 2001, as amended by Decree No. 4946 of 2003 which created the Board of Management of Genetic Heritage - CGEN (ASSAD & SAMPAIO, 2005).

The Brazilian Federal Constitution of 1988, Chapter on Environment, Article 225, paragraph 1, item II, states that the government and the community have a duty to preserve the diversity and integrity of the genetic patrimony of the country and

supervise the institutions engaged in research and manipulation of genetic material. This means that the protection of genetic resources is at the height of the legal system of the country. This device was regulated by Law No. 9985 of July 18, 2000, which defines biological diversity.

The Convention on Biological Diversity (CBD) was ratified in Brazil by Decree. 2.519/98. Since signing the CBD, several attempts have been made to regulate the access to genetic resources.

However, the entry into force of the Provisional Measure No. 2.186-16/01 stops all projects in progress in national congress. In 2000, there were many protests from scientists and civil society in general, due to the operating contract for genetic resources of the Amazon between the social organization Bioamazônia - commissioned by the federal government to manage the Brazilian Program of Molecular Ecology for Sustainable Use Biodiversity of the Amazon - and the multinational corporation NOVARTIS PHARMA AG. Given these intricacies, the Executive Branch issued Provisional Measure No. 2.052/00, which was reissued without change monthly until April 2001, when it started to change until August 2001. However, since then, by virtue of Constitutional Amendment No. 32, dated September 12, 2001, access to genetic resources and traditional knowledge in Brazil is regulated by Provisional Measure No. 2.186-16/01 in his 16th reissue (Castilho, 2008).

This Provisional Measure was regulated by Decree No. 3,945, of September 28, 2001, article 10, which defines the composition of the Board of Management of Genetic Patrimony (CGEN), a federal agency linked to the Ministry of Environment, and establishes the standards for their operation, and subsequently received updates through Decree No. 4946, of December 31, 2003. The Provisional Measure regulates the activities regarding access to genetic resources through Decrees, Resolutions, and Resolutions of the Technical Guidelines, the latter three approved by CGEN (ASSAD & Sampaio, 2005).

In this context, it is important to mention the Law no. 11,105, March 24, 2005, establishing safety standards and mechanisms for monitoring activities involving genetically modified organisms - GMOs and their derivatives, creating the National Biosafety Council - CNBS, restructuring the National Technical Commission on Biosafety – CTNBio establishing a National Biosafety Policy - GNP and, for the purpose

of disciplinary sanctions against harmful conduct and activities to genetic resources or associated traditional knowledge. Decree No. 5,459, of June 7, 2005, regulated article 30 of the Measure Provisional No. 2186-16.

The Provisional Measure No. 2186-16 also ensures the rights of indigenous and local communities requiring an indication of the source of access to traditional knowledge in all publications, uses and exploitations. Moreover, it prohibits testing and research related to traditional knowledge by unauthorized third parties, as well as any dissemination, transmission or retransmission of data and information that comprises or is associated with traditional knowledge which is in the direct ownership of these communities (SANTILLI, 2007).

For access to traditional knowledge or genetic heritage components for scientific research and technological development of bioprospecting activities, Provisional Measure No. 2.186-16/01 emphasizes that foreign groups, institutionally unaffiliated researchers or research agencies and individuals can only claim access to these resources if they are linked to a national research institution.

Regarding the shipment of materials for research regulated by MP No. 2186-16, the shipment of samples of components of genetic heritage destined for scientific research, bioprospecting or technological development must comply with the rules specified in the standard, while sending herbarium specimens for morphological analysis does not need to follow the specific regulations established by the MP.

The most accentuated criticism of MP regards the consent of the holder of the area from which to remove the material for research and is based on the following arguments: difficulties in identifying individuals responsible for the area, in mapping the area where the material will be removed for research and, of course, the advancement of research to recognize the area firstly for the application for approval and secondly for material collection. However, the argument supporting this claim is the legal nature of the genetic heritage and the need to encourage the conservation of biodiversity.

Due to the origin and nature of transaction costs and the limited rationality of agents, there is the risk that opportunistic behavior may not be accurately assessed nor the consequences of the behaviors of other actors involved in the transaction predicted. There is thus a need to create mechanisms that can minimize these

uncertainties by providing a flexible (contract?) structure that can adapt to unforeseeable circumstances.

There are also uncertainties because genetic resources themselves are evolving. Because of this it is not known which properties will be useful in the near future. For this reason, there is also the difficulty of valuing these resources. Another important point is that no complete information is available and completed on the natural resources, which creates enormous difficulties related to the construction of contracts that can be met.

In this context, the problematic definition of property rights leads to long-term returns being penalized through distortions in the investment profile. Investments are made in bioprospecting, mostly in various stages of research, from the collection of the input, the laboratory tests, the preclinical and clinical testing, until the final product reaches the consumer. All these stages are distinct and can be developed by different institutions or by a single institution. In this sense, the return associated with them depends on the maintenance of property rights, because any vagueness leads to increased uncertainty and contractual maintenance costs.

In order to decrease this level of uncertainty, there is a need for contractual and organizational forms that are flexible, allowing for adaptations and changes during the process, thereby reducing transaction costs and increasing the interest of the parties to remain in the process.

Since the CBD, many contracts have been signed. Despite the fact that the Convention clarifies a set of principles for the allocation of property rights relating to the use of genetic resources, bioprospecting negotiations are not always successful, either because contracts are not up to expectations in terms of financial returns, or because the agreements remain contradictory.

CONCLUSION

After examining the issue it is clear that the practice of bioprospecting brings in its wake a number of uncertainties, considering that the genetic resources themselves are evolving. Because of this it is not known which properties will be useful

in the near future. For this reason, there is also the difficulty of valuing these resources. Another point is there isn't information available about traditional knowledge and all the natural resources, which creates enormous difficulty in drafting contracts that may be signed bilaterally.

It should be stated that both during the drafting and signing of long-term agreements, there is a need for an effective advisory agency, particularly with regard to public property. Another key point to be observed in such contracts, is that institutions have the opportunity to develop contracts that are changeable and subject to renegotiation in the process, thereby reducing transaction costs and mitigating the uncertainties and risks of opportunism by the parties (in order to avoid repeating such occurrences as the illegal contracts signed between Bioamazônia and NOVARTIS PHARMA AG.)

It is imperative that countries seek a balance between the conservation and sustainable use of the environment on the one hand, and scientific and technological interests and market forces on the other, and that Brazil, being a signatory to both agreements, seek only to sign contracts with other signatories to the Convention on Biological Diversity and the TRIPS respecting its principles.

It is worth mentioning that there is real need to seek development that is economically sustainable and to align existing bioprospecting contracts with a new international law of the environment that incorporates both present and future concerns.

Finally, as suggested by Rafael Costa Freiria (2003), international bioprospecting contracts offer the opportunity to set certain limits, such as in terms of mitigating contractual autonomy in choice of forum clauses to prevent fraud against jurisdictions that have more stringent environmental protection standards, discussing the pressing need for good faith in bioprospecting contracts in view of preserving the culture of local communities, as well as of achieving equality in the distribution of benefits from the exploitation of biodiversity. Such efforts would further the search of a situation of better balance between capital-owning investors and biotechnological mechanisms on the one hand, and the party that seeks equitable exploitation in their areas of biological diversity on the other.

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