



Access to Genetic Resources in Latin America and the Caribbean: Research, Commercialization and Indigenous worldview



IUCN's Regional Office for South America



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**Access to Genetic Resources in Latin America and the Caribbean:
Research, Commercialization and Indigenous Worldview**

**Strengthening the Implementation of Regimes of Access
to Genetic Resources and Benefit Sharing in Latin
America and the Caribbean**

Montserrat Rios and Arturo Mora

Editors

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Biodiversity research in megadiverse countries:
strategies for scientific and technical alliances



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Biodiversity research in megadiverse countries: strategies for scientific and technical alliances

1. Introduction

Strengthening scientific and technological capabilities in the countries of origin of genetic resources is strategic, particularly to fulfill the commitments of the Convention on Biological Diversity (CBD). However, biodiversity research has limitations resulting from the development and implementation of the commitments in the CBD itself. In this sense, any restrictions affect both the researchers from the countries of origin of genetic resources, as well as the scientists from countries that use biodiversity, because the impacts and approaches to their solution are not homogeneous. As a result of such situations, scientific and technological capabilities required for the conservation and sustainable use of nature in these countries are still pending.

The megadiverse countries are often characterized by high biodiversity indicators; worrying levels of poverty and corruption; scarce scientific and technological research skills, and belonging to a CBD category of providers of genetic resources. When compared to countries with advanced technology but little biodiversity, the latter are identified as users having an interest in the access to genetic resources. Nevertheless, the interest of suppliers also emerges to participate in the benefits derived from the access to modern biotechnology, and it becomes necessary to propose a mutual compensation. The differentiation of these types of countries was implemented through the CBD on the obligations of the supplier countries (Art. 15, 2) and the obligations of the user countries (Art. 15, 7 and 16), establishing a distinction that is reflected in the background of international negotiations and regimes on access to genetic resources and biological material (Martínez and Biber-Klemm 2010; Biber-Klemm *et al.* 2010).

In accordance with the aforementioned description, the policies of international organizations prioritize the implementation of biodiversity inventories in supplier countries with the purpose of better exploiting its potential use in the industry. Thus, governments, businesses and individuals in user countries led research and bioprospecting activities which in some cases included the patenting of research results and genetic resources, but without agreeing on a fair and equitable sharing of benefits with the countries of origin as envisaged by the CBD. In turn, the countries of origin of genetic resources focused on designing schemes and defensive measures in order to avoid misappropriation and protect their associated traditional knowledge. The objective in itself is to regulate access and ensure the sharing of benefits arising from their use.

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Access regimes generate unexpected effects on national research systems, because they do not encourage research and innovation (Martinez and Biber-Klemm 2010). At the same time, they have lacked an effective international regime that works beyond national jurisdiction until now. Additionally, the technical and scientific developments in areas such as genomics, bioinformatics and synthetic biology, as well as the standards and dynamics of international research, have made some of the provisions established to control flow, transfer and utilization of genetic resources and its associated information obsolete.

In this context, the present study outlines the difficulties that scientific research faces following the negotiations which led to the CBD and the definitions on the subject of access to genetic resources. Thus, it tries both to establish criteria to differentiate scientific and commercial research, such as finding regulations designed to promote and support scientific research in order to strengthen scientific and technological capabilities in the countries of origin of biodiversity. Also, the scope of Art. 8 (a) and its relationship with Art. 23 of the Nagoya Protocol is analyzed to understand scientific research as a part of the innovation value chain and its development, as this is the basis for a differential treatment. After this analysis, the prevailing standards and practices in scientific research are contrasted with relation to the budgets of access regimes that seek to control and monitor the use and exploitation of genetic resources and associated knowledge.

Being able to show the unintended effects of access regimes is achieved by describing two cases of scientific research in countries of resources. The first is an exploration project conducted by an international institution in a nature reserve in Ecuador, entitled "Global Ocean Sampling Expedition, Galapagos National Park: collection activities and implementation of legislation." The second is a project developed by a national institute in Colombia, entitled "Research on a microorganism of the genus *Lactococcus* sp., Institute of Biotechnology, National University of Colombia."

Both case studies document the details on what happened in Colombia and Ecuador, becoming a reference for analyzing the scope and potential of the provisions included in the Nagoya Protocol on facilitating access to scientific research. The characteristic elements of two solutions to facilitate both access to biodiversity as well as scientific research, revolve around the problems illustrated. One of the solutions is led by researchers from a user country, while the other was elaborated by a country of origin of genetic resources.

The results suggest the need to overcome the dominant characterization which identifies megadiverse countries as suppliers, since this emphasis has implications for international negotiations and national decisions on biological research and biotechnology development. Thus, the final considerations will highlight what are the main problems faced by exploration of biological and genetic diversity, emphasizing the need and opportunity for the countries of origin of resources to become stronger at a scientific and technological level.

In summary, the case studies indicate that regulations in the regimes on access to genetic resources must be aligned to the objectives of the CBD in megadiverse countries. This is why we must strengthen endogenous scientific-technological capacities applied to research on biodiversity and its sustainable use to generate profits. Achieving this is crucial, but requires a serious commitment from user countries with advanced technology to build programs and cooperation mechanisms, all of which will aim at removing existing asymmetries with their peers in the supplier countries.

2. Scientific scenario and the subject of access to biodiversity

Researchers who promote a facilitated access to scientific research from countries considered users of biodiversity encounter a definition of genetic resources in Art. 2 of the CBD that is very general (Martinez and Biber-Klemm 2010). In particular, it is reported that the term includes any biological material with microbial or different functional units of heredity, deoxyribonucleic acid (DNA) or ribonucleic acid (RNA), whether from plant, animal, microbial or other origin, but all having real or potential value. From this point of view, all research using samples having functional units of heredity would be within the framework of the access regimes (Martinez and Biber-Klemm 2010).

In this scenario concerning access, the perspective of researchers conducting scientific research on biodiversity in megadiverse countries is controversial, because they question countries of origin for extending their rights to the biochemical products –as is the case of Costa Rica– or other derivatives such as synthetic molecules –like in the case of the Andean Community (CAN). Similarly, during a meeting in Germany in 2008, a group of research institutions expressed concern about the broad interpretation of the terms “utilization of genetic resources” under the third objective of the CBD. This precedent led to the Nagoya Protocol to define its meaning in Art. 2 (c) as “conducting research and development on genetic resources and/or on the biochemical composition of genetic resources, including their application through biotechnology as defined in Art. 2 of the CBD.”

For countries rich in biodiversity, the legal definitions of the object pose access difficulties from the point of view of control, monitoring and resource monitoring given technological advances and research practices. The proposal of regulations for Decision 391 of 1996, developed at the National University of Colombia (Nemogá-Soto 2010), highlights the need to formulate a definition that reflects technological advances. It also refers to genetic information when defining genetic resources and seeks a comprehensive regulation for biological organisms, genetic material, genetic information and byproducts. The elaborated definition considers new technological realities and identifies biogenetic resources as: “any biotic component of a biotic system from the molecular level to the biome and its genetic information, of real or potential value or utility, which is contained in samples of a full or partial viral, microbial, fungal, plant or animal specimen in the form of extracts, molecules or substances produced by its metabolism, and which have been obtained naturally or synthetically from dead or living organisms, whether they are under *in situ* or *ex situ* conditions” (Nemogá-Soto 2010). In itself, this approach is based on Decision 345 of 1993 which foresaw the establishment of a common regime on access to biogenetic resources in the countries of the CA.

The above definition recognizes a technological fact that is omitted in access regimes and can make them dysfunctional, since the definition of genetic resources in the CBD is limited when facing the technological versatility that allows access to the encoded information in DNA and other derived molecular structures, since once it has been accessed it is used for commercial purposes. It is worth noting that some definitions of genetic resources remain anchored in outdated genetics _which disregard the development of genomics, bioinformatics and synthetic biology; but it must be said that Pastor and Ruiz (2009) presented a pioneering study on this issue in the region which the Nagoya Protocol analyzed in the context of its negotiations, but with little practical results.

The concern about the definition lies in the implications for different stakeholders. In the case of the countries of origin of genetic resources, there are implications regarding the exercise of rights and the achievement of objectives such as a fair and equitable benefit sharing arising from the utilization of resources and products. In the case of users interested in access for research or commercial developments, the implications are manifested in terms of procedures and authorizations required for its use, because they must avoid legal disputes and ensure legal guarantees over the eventual commercialization of resources or research results. In this respect, conventional definitions resulting from negotiation –not from scientific validation– are used. For instance, although one may question the scientific basis of the distinction between biological and genetic resources, several regulations contemplate and establish parallels and different regimes for access (Nemogá -Soto 2008).

It is the economic and technological context of the use of resources and research results that turns the definition into a subject to negotiation. This is why the definitions of the CBD are the result of arduous negotiations that include concepts influenced by an economic perspective. For example, the concept of genetic resources refers to the actual or potential value; but in practice, recombinant DNA or genetic material has potential uses in commercial applications because of the applied biotechnology, regardless of what biological organism it is. Within this economic and technological scenario, it becomes difficult to differentiate between commercial and non-commercial scientific research because research activities are adding value and information to the genetic material.

3. Distinction between commercial and non-commercial research

At present, it is necessary to find a clear distinction between non-commercial scientific research and commercial research oriented to product development as criteria for exceptional treatments in access to genetic resources; seeing as in the case of bioprospecting and biotechnology linked to the development of new biochemical compounds, such differentiation is less clear. The definition of non-commercial research, given by research institutions in biodiversity during the negotiations of the Nagoya Protocol, matches the operative and unapproved text of the Eighth Meeting of the Ad Hoc Open-ended Working Group on Access and Benefit Sharing (CBD 2009), stating that the purpose is to increase public knowledge without intending to establish restrictions or property rights (CBD 2009). Operationally, the definition emphasizes a subjective element and focuses on the control or dissemination of research results.

Leary and colleagues (2009) proposed to examine the scientific and commercial interest in research on marine genetic resources based on a review of literature and patent databases. This analysis covers bioprospecting activities, including everything, from sampling conducted by academic institutions with public funds to developing and marketing products for the biotechnology industry. The team found that during phases of isolation, characterization and culture of microorganisms, laboratories -regardless of whether they are financed by public or private resources- participate. However, the results of scientific research – called basic by some– made it possible to establish the Verenum Corporation which markets Fuelzyme™, an enzyme that comes from marine genetic resources collected from public funds (Leary et al.2009)

At the same time, Lopez Cabrera Medaglia and Silva (2008) highlight the difficulty of separating basic from commercial research which stands out as a persistent problem in the various access regimes, and indicate: "A more general question is whether scientific and commercial research must be differentiated. While this is desirable to encourage scientific research, the distinction is not always obvious. Often, scientific research leads to subsequent marketing "(Dross and Wolff 2005, quoted in Lopez Cabrera Medaglia and Silva 2008).

The scenario of funding for biotechnology research has changed leading to greater private capital investment particularly in countries with developed technology, making it difficult to distinguish the sources of funding. The growing on private capital of genetic research common in this day and age, dependence changes the dynamics and standards of the dissemination of scientific results because and confidentiality and restrictions arising from the application of intellectual property regimes are becoming more widespread. Several factors influencing this change are: the alliances of research institutions with the industry; the participation in trade initiatives; the use of patents and plant breeders' rights as indicators of academic productivity and institutional prestige; the institutional promotion of biotrade programs and the viability of business initiatives stemming from research results. These factors, as a whole, have the effect of restricting the free exchange of results and materials among researchers and institutions; reaching effect where the institutional and legal context in which it the activities of use and exchange of genetic materials, information and access to results unfold, is increasingly characterized by a tension between an open dissemination system and a proprietary system for biological material and associated information (Welch, Shin y Long 2012).

An owner is the system that supports the sovereign rights of countries of origin in the CBD and in turn implies responsibility for the conservation of biodiversity; under this objective, participates in the distribution of benefits, and it counters actions of misappropriation of resources and traditional knowledge. Thus, the distinction between commercial and non-commercial research is problematic for countries of origin, which is why it is necessary to establish differences based on the use of genetic resources, but –just like with other distinctions which emphasize subjective aspects– the difference ends up being focused on the declared intention at the beginning of the research. For the above reasons, López Cabrera Medaglia and Silva (2008) suggest: "Choosing intention as the defining criterion will establish a clear and predictable situation for the researchers and the industry receiving biological material." Also, you must also consider the difficulty of determining the intention for each sample transfer and use of the material once it leaves the country. A subjective test does not provide legal certainty for any of the parties involved in the access contract negotiations and execution.

At present, it is still required to establish essential differences between commercial and non-commercial research. This is why, when one must distinguish between biological and genetic diversity for trade, one opts for listing just basic common features including:

- i. Both los cases require access to genetic resources and associated traditional knowledge.
- ii. Collection and analysis generate information and increase the value of the resources.

- iii. Research methods are: collection, identification of reference specimens, biochemical analysis and genetic sequencing.
- iv. Research centers and universities can do both commercial research and non-commercial indistinctively.
- v. The research results are likely to be applied to the conservation and sustainable use of biodiversity.
- vi. The result of the investigation may acquire commercial value and become a private appropriation through intellectual property rights.

The types of commercial and non-commercial research differ when the results are focused on obtaining profit, which display distinctive characteristics such as:

- i. Confidentiality and control over research results and information.
- ii. The dissemination of the research is subject to directives on intellectual property, particularly in the interest of applying for patents or preserving trade secrets.
- iii. The exclusive property rights over industrial applications and over derived economic benefits.
- iv. The reserved and restricted access and transfer of reference specimens and associated information.
- v. The privileged transfer of material and information to business partners.
- vi. Agreements with commercial or industrial partners for research on specific uses or scaling of production.

In summary, all the above elements are only observable during the research process or after results are obtained, but they do not contribute to differentiating their type at the starting point of access to genetic resources or derivatives (UNEP/CBD 2008). In other words, these features do not provide criteria to distinguish between commercial and non-commercial research stated in access requests.

4. 4. Facilitated access to scientific research

From their inception, regimes developed in exercise of sovereign rights recognized in the CBD arouse concern among researchers, especially regarding possible restrictions on access and exchange of genetic resources (Rull and Vegas-Vilarrúbia 2008). In themselves, access regimes focus on ensuring benefit sharing arising from the use of genetic resources and on countering situations of illegal appropriation and exploitation. This is the reason why some research institutions and researchers respect the rights of countries of origin and of indigenous and local communities accepting and adopting guidelines for observation. In the context of international negotiations, the signatories of the CBD adopted the Bonn Guidelines at the Conference of the Parties COP 2002, on a voluntary basis. Thus, they abide by some international institutions adopting best practice protocols and parameters to observe the regulations on access for its researchers (Vale, Alves and Pimm 2008; Biber-Klemm *et al.* 2010).

The voluntary scheme and its exceptional adoption appears to be unsatisfactory for megadiverse countries, particularly with respect to fair and equitable benefit sharing; so, actions were promoted at the World Summit on Sustainable Development in 2002 in order to adopt the decision of establishing an international regime on access. Subsequently, negotiations are aimed at ensuring that national regulations pertaining to access and benefit sharing, referring to the use of biological material, genetic resources and derivatives, are met, thus encouraging scientific activism in international forums (Jinnah y Jungcurt 2009). Welch, Shin and Long (2013) indicate that the establishment of an international regime on access in order to make benefit sharing effective has global implications, including countries that are not part of the CBD. One of these cases would be the United States of America, a country that has yet to ratify the CBD, and whose researchers would be subject to the measures of the Nagoya Protocol once it enters into force when they require to collect, exchange and use genetic resources in countries who are Parties to the CBD.

Concerns about restrictions on access regimes are also expressed by researchers from the countries of origin of genetic resources, because their ineffectiveness has led to a substantial part of their research being illegal due to lack of appropriate access contracts. In some cases the environmental authorities have imposed sanctions on researchers and research institutions (MAVDT 2010), generating an increasing lawlessness in the projects developed by local researchers. When analyzing the asymmetries between countries of origin and user countries in terms of research capabilities, funding opportunities and division of labor, it is shown that they vary for researchers depending on the context. However, there is consensus on the fact that an access regime with high transaction and time costs does make it impossible to establish cooperation agreements and international research programs.

5. Capacity building in countries country of origin

In response to the concerns of researchers in the international context, Art. 8 (a) of, the Nagoya Protocol plans to introduce an exceptional treatment for non-commercial research in the regulations on access, stating that: "It will create conditions to promote and encourage research which contributes to the conservation and sustainable use of biological diversity, particularly in developing countries, including through simplified measures on access for non-commercial research purposes, taking into account the need to address a change of intention for such research".

In line with the objectives of the CBD, Art. 8 (a) establishes a commitment for all countries party to the Convention to constitute conditions that promote research, thus contributing to the conservation and sustainable use of biodiversity. However, although the commitment includes all countries, the references to developing countries in particular suggest that it is there that scientific and technological scenarios should take place. Thus, Art. 8 (a) illustrates the conditions that can promote and encourage research, referring to measures on access for non-commercial research purposes, but their establishment is up to the countries with access regimes since in practice it is their obligation as the owners of biodiversity.

When raising the issue of a differentiated treatment for non-commercial research, the Nagoya Protocol anticipates that the intention may change, especially due to the discovery of results with commercial potential (CBD 2009). Since this is a subjective aspect, if this intention is not voluntarily declared, it is difficult to establish the change in direction. In order to address this issue, the design of access regimes and regulations must identify objective indicators of commercial intent to be included in the mutually agreed terms (MAT) (UNEP / CBD 2008). The following are some of these indicators:

- i. The restrictions on the dissemination of research results, for example agreements of reserve or confidentiality of results.
- ii. The limitations on the participation of researchers from the supplier country as collaborators or coauthors.
- iii. The publication of the results without allowing preliminary access to such results by the authority of the supplier country.
- iv. Delays in the public dissemination of the data resulting from the research.
- v. The payment of high fees for access to data, technologies or materials resulting from research.
- vi. The retention of monetary benefits from the sale or transfer of economic benefits, patents, or licenses stemming from research findings.
- vii. The transfer of material to commercial partners.
- viii. Contracts with reserved rights to apply for patents or to have control of intellectual property rights (IPR).
- ix. Research on commercial application, contracts with a commercial entity or stakeholder, or the realization of market research.
- x. Product development or technology testing as part of a broader undisclosed project.
- xi. Forms of contractual restrictions on the dissemination and subsequent use of the results.

In line with the Nagoya Protocol, access regimes and regulations must identify the indicators that show the change of Intention in the research. The same situation arises in connection with marketing indicators for byproducts, namely non-genetic resources derived from genetic ones and which are subject to the fair and equitable benefit sharing (CBD 2008). Here are some examples:

- i. Marketing and market availability or sale to the public.
- ii. Seeking approval for marketing or other authorizations such as product registration.
- iii. Filing for intellectual property protection.
- iv. Identifying a specific use for a byproduct.

Due to its scope in designing policies and making decisions on access regulations, it is pertinent to read Art. 8 (a), in conjunction with the provisions of Art. 23 on technology transfer, collaboration and cooperation, because it allows you to define actions to strengthen the capacities of countries identified as suppliers. Art. 23

of the Nagoya Protocol states that the parties will collaborate and cooperate in technical and scientific research, and development as a means to achieve their goals, particularly in developing and insular countries to improve their technological and scientific basis.

The language used in Art. 23 differs from the one used in Art. 8 (a), because the former promotes conducting research in the countries of origin of genetic resources, as long as research is possible and appropriate when pointing out that the parties seek to promote and advance access to technology. The terms used are lax and its wording –incorporated in the Bonn Guidelines– leaves voluntary commitment in this area unchanged (Secretariat of the Convention on Biological Diversity 2002). In other words, Art. 23 does not generate enforceable commitments for countries possessing technology and involving their obligation to contribute to strengthen the technological base of biodiversity-rich countries. In contrast, Art. 8 (a) incorporates an enforceable obligation is that biodiversity-rich countries establish simplified measures on access for research purposes.

In accordance with Art. 23 of the Nagoya Protocol, Art. 8 (a) also reiterates a concept which characterizes international negotiations in which countries rich in biodiversity are considered primarily suppliers. This is also assumed by researchers from developed countries when they urge for access to genetic resources for research purposes to be facilitated, because in scientific publications they set themselves apart from scientists from countries identified as suppliers (Jinnah and Jungcurt, 2009; Martínez and Biber, 2010). This difference in perspective is historical and evidences the asymmetries between researchers from developed and developing countries in terms of research priorities, division of labor and shared authorship of results (Jinnah and Jungcurt, 2009). Art.8 (a) does not go beyond this view, since the assumption of this rule pertains to supplier countries with limited scientific capabilities and user countries of biodiversity, without the latter acquiring effective commitments to strengthen the scientific and technological capabilities of the former (CBD 2009) .

Decision-makers of public policy decisions and access legislation have an opportunity in this area, especially for countries rich in biodiversity to develop, as provided in Art. 8 (a), in a manner that satisfies the priority and need to strengthen their capacities. In itself, the strengthening of scientific and technological capacities and research on biodiversity in their countries, becomes a requirement for the exercise of the sovereign rights of the country (Unimedios, 2009). In carrying out Art. 8 (a), the biodiversity-rich countries can establish clear parameters to facilitate access to genetic resources for scientific research, taking into account that their participation is a priority in programs and projects, and is not limited to being just a supplier of resources or facilitating access to associated traditional knowledge. Therefore, if all this adds to the perspective of Art. 6, the situation must be instrumented so that the prior informed consent (PIC) and MAT jointly contribute to strengthening national capacities. The two instruments are necessary when considering the eventuality of a change of intention in research, the use of third-party resources and the forecasts of availability of research results for public access.

6. Scientific research and the addition of economic value to biodiversity

Scientific research on biological and genetic diversity can be analyzed in terms of its role in the generation of innovation and the creation value. This is why Martinez and Biber-Klemm (2010) see it as part of a value chain which adds to the amount resources. The process begins with basic non-commercial research, followed by scientific and technological development and ending in the marketing of products (UNEP / CBD 2008). The scheme for adding value is parallel to the generation of innovation, because it starts with the resources and expertise found in local indigenous communities, continues with the scientific activities of collection of biological material and associated specimen identification and classification of information, and experimentation. Later, it continues with the genetic characterization and isolation of its components according to their potential uses, and it end with the development and testing of industrial and biotechnological applications, scaling and commercialization. In this chain of value addition and innovation, researchers have a key role since they participate in every step of the process and generate new results for science.

The results of the research are published in accordance with the existing compromises with the sponsoring entities and, once disseminated, they are integrated to technological development globally. The results of the research are published in accordance with the existing compromises with the sponsoring entities and, once disseminated, they are integrated to technological development globally. At the end of the value chain, if the results of scientific exploration produce marketed products, linkages between the place of origin of the resources and the initial knowledge of the communities dissolve, and access regimes become less relevant. This also occurs when there is genetic information likely to be transferred between researchers or stored in public databases. An example is when the concept of a taxonomic conservation research, faces the same requirements and restrictions as another that is aimed at marketing resources or results with emphasis on its economic process. The point of differentiation continues to be subjectivity of the researchers, since while Martinez and Biber-Klemm (2010) pointing out that research on conservation and sustainable use is irrelevant and has no commercial use, this argument is sometimes used to justify an exception to the requirements of access and facilitate research in taxonomy, ecology, population genetics and evolution, opening the possibility for non-commercial research in genetic and pharmacological engineering (Secretariat of the Convention on Biological Diversity 2007). This is why, the difficulty with certain research arises when resource information would have to be admitted, but not added to the value chain.

On the levels of political decisions when applying Art. 8 (a) of the Nagoya Protocol, the need to define in which areas it is suitable to facilitate access to strengthen capacities in research and development should be considered as a key aspect when regulating access to genetic resources. From Art. 8 (a) no inflexible orientation or single model for countries to establish access regimes may be derived, but it enables them to facilitate and strengthen national research while being aligned with the Nagoya Protocol. Thus, endogenous capacities will benefit greatly, making it easier to track all the process, from research to innovation through a control of the use of genetic resources, their byproducts and associated knowledge. Currently, the assumptions of access regimes are overwhelmed by the standards and practices of scientific research.

7. Standards of current activities in academia and science

Scientific research is based on standards and practices that go beyond the provisions included by countries in their regimes of access to genetic resources, making it difficult to control the transfer and use thereof. Research institutes and universities are working with the assumption that research results should be published. Very often, scientific journals require the deposit of sequences of genetic information during the evaluation process of the articles. This is why, this becomes an unquantifiable reservoir of free access to the user community, researchers and businesses. The main databases of genetic information (primary) are: GenBank in the United States, coordinated by the National Institute of Health; EBI-EMBL in Europe and DDBJ in Japan. The three databases are synchronized periodically and have similar information, coordinating some of their activities through the "International Nucleotide Sequence Database Collaboration" (INSDC) (<http://www.insdc.org/policy.html>). In addition, the Swiss Prot database excels in the field of protein and there are more than 3000 secondary databases with genetic information of varying scope.

Generally the information in the database is publicly accessible and has few restrictions. However, it does not mean that all entries are free to be used. On the contrary, some nucleotide and amino acid sequences have been set aside for patent applications or patents have already been granted. One example is the recent release or version of the European database EBI-EMBL, of entries 266, 255, 715 and 24, 746, 595 which are sequences for patents or patent applications; out of nucleotides 499, 882, 374, 645 included in the version or "release" No. 114, of December 2012, 2.5% –this means 12, 530, 222, 966– correspond to patents which have been granted or are pending (EBI-EMBL 2012). Having a lot of information available is useful for knowledge, conservation and the sustainable use of biological diversity, but it involves legal and ethical challenges. In particular, it involves changes from the traditional conception of scientific endeavors who are now welcoming 20 year-old CBD standards, or Decision 391 of 1996, which has existed for 16 years.

New technologies used in bioscience and biotechnology research are increasingly common in developing countries as they use tools such as bioinformatics (Restrepo et al., 2009) to analyze information and help solve biological problems, since the cost of these *in silico* techniques is lower in comparison to *in vitro* or *in vivo* experiments. For instance, in the case of Colombia, there are several groups of professionals from universities and research centers who have been working since 2007 on issues pertaining bioinformatics, genomics and other "omics" (proteomics, transcriptomics and metagenomics, etc.) at the GEBIX network, the Colombian Center for Genomics and Bioinformatics of Extreme Environment, with the participation of the Universities of Caldas; Cauca; Valle; the National University and the Javeriana University, as well as private institutes such as Corpogen and Parquesof (Benítez-Páez and Cardenas Brito 2010). Also, during these years the following institutions were created: the National Genome Sequencing Center at the University of Antioquia (2010), the Colombian Center for Bioinformatics and Computational Biology located in Manizales, Caldas (2010) and a master's program in bioinformatics and computational biology at the National University of Colombia in Bogota (2012), a pioneer in the country (<http://www.agenciadenoticias.unal.edu.co>).

In this context, some scientific institutions with collections of plant, animal and strain germplasm transfer biological material (organisms or parts) as a regular necessary practice for their activities, whether it is for backup or specimen for taxonomic analysis by specialists from foreign countries. The exchange takes place informally, as it is motivated by close relationships between colleagues. For instance, a recent study in the United States of plant non-genetic resources, which involved more than 400 professionals from federal institutions and universities established that the use of a Material Transfer Agreement (MTA) the PIC is low, even among those who have formally adopted its use (Welch, Shin Long 2013).

The requirement of access regimes since the Nagoya Protocol and the increasing adoption of regulations pertaining to intellectual property in research institutions, tends to reduce the informality of exchanges since it guarantees contractual clauses for the management, transfer and control of the material received. Additionally, funders increasingly include the practical use of research results and their transfer to the productive sector; for example, when capital is private, both the data and the results can become part of the economic assets of the company. Also, the restriction in publication is a practice observed by researchers in various fields, particularly if there is investment of private funds, tending to add to the limitations that may be imposed by countries of origin of genetic resources interested in enforcing their rights of sovereignty.

Some practices in research processes contradict the assumptions of access regimes, for example with provisions contained in Decision 391, which limit it to a certain period of time and then demand that the samples be returned or destroyed after the completion of the project. In itself, this requirement contradicts the direction of institutions and researchers who invest time and resources in the collection and preservation of material whose information can be used scientifically to address new questions or train other researchers.

8. Status of national research in Colombia

Access regimes elaborated to control the use and misappropriation of genetic resources and associated traditional knowledge, are largely misunderstood by national researchers because, from their point of view, research on biodiversity does not only satisfy their intellectual curiosity and provide new knowledge, but it also implies the free exercise of their right. The regulatory frameworks to enforce the sovereign rights of countries of origin of genetic resources and the obligations of the States with their indigenous peoples are beyond their quest for knowledge about the biological reality. The assumption of researchers is that biodiversity is a natural object of research, with indigenous peoples and local communities constituting the social context where the studied natural phenomena occur. Thus, the protocols to be followed, the rights of indigenous peoples and local communities, the consents and environmental permits to be obtained, are experienced as a complex, costly and illogical social and institutional reality (Chacón y Toro 2009).

In this complex national scientific scenario, being unable to conduct a research proposal, after securing financial and institutional support and overcoming a number of difficulties and difficult situations because of not getting the contract for access to genetic resources or not conducting the prior consultation can be a frustrating experience for a researcher. In practice, funds raised for

research after investing time and resources, are jeopardized by the impossibility to meet timetables due to delays in obtaining environmental permits.

One consequence is that access regimes may affect the competitiveness of the national researcher in terms of knowledge production, for example when the research has to restrict sampling methods or sites to be outside the scope of the concepts of genetic resources, byproducts or access. The research results may lose specificity and recognition, particularly when molecular techniques involving access to genetic resources are excluded. The delay in obtaining access contracts may have negative effects on the relevance of the research, as it may lose novelty and relevance in the state of the art (Acosta 2009). Other effects on research methods are related to the natural processes that take place in certain ecological cycles, where the delay in processing authorizations may prevent carrying out the experiments and collections within the prescribed period (Franco 2009). Finally, the uncertainty regarding the requirements and the time for procedures make it impossible to make the calculations needed to plan scientific activities.

In the case of Colombia, it has been determined that the procedures associated with the rights of indigenous peoples and local communities, such as prior consultation and PIC, are perceived negatively by researchers. Nemogá-Soto (2013) presents an analysis of genetic biodiversity research and policy in the country (period 1991-2010), evidencing the omission of the rights of indigenous and black populations in research processes on their knowledge and genetic resources. Thus, on several projects it was decided to exclude Afro-descendant and indigenous territories from the sampling areas; so, out of nine cases of access contracts requiring consultation, only three were conducted and in the other six, collective territories were eliminated from the study areas (PLEBIO 2012).

The researcher is unaware of the legal and political parameters that commit the State to indigenous peoples and local communities, and so the researcher does not realize that his research could affect their cultural integrity or lifestyle. Also, scientists must recognize that these human populations are the rightful holders of collective rights over their lands and resources. Some positions in academia have even proposed the open rejection of access paperwork and legal procedures, ignoring that this guarantees fundamental rights of indigenous peoples (News Agency National University 2012).

The status of research on non-human genetic diversity in Colombia illustrates the unanticipated effects on the scientific and technical capacities in countries of origin, especially those who designed and approved the access regime set out in Decision 391. One effect is to generate illegality in the research, caused by the lack of functionality of access regimes in the Andean countries. Thus, a regulatory analysis by the National University of Colombia in 2009 found 565 projects registered in the database of ScienTi COLCIENCIAS, all of which had genetic resources without authorization, with the study being conducted at the request of the Ministry of Environment, Housing and Territorial Development, now known as the Ministry of Environment and Sustainable Development (MADS). The same database revealed that 13.7% of the research groups related to biology and related sciences, as well as belonging to five National Programs of Science and Technology, have irregular access to genetic resources, particularly with respect to biotechnology and agriculture (Nemogá-Soto 2010).

During 2012, the first contract for the purpose of industrial application and commercial use for the project was signed under the name "Research on a microorganism of the genus *Lactococcus sp.*, Institute of Biotechnology, National University of Colombia" (Nemogá-Soto y Rojas Díaz 2013). In March 2013, the public database on access to genetic resources of the MADS registered 56 signed contracts being awarded for scientific research without commercial interest. However, some cases which allow bioprospecting are included within this category. The research of the first 47 contracts signed during 2012 is divided into the following topics: taxonomy, evolution and systematics (20), population genetics (13) and ecology (1); the remaining 13 have either the interest of applying or solving a specific problems, such as the identification of microorganisms that perform particular activities; the characterization of substances with a pharmaceutical use and a contribution to human medicine. Also, the 47 contracts were implemented by researchers from public and private universities, research institutions, public health agencies and environmental authorities.

With the exception of one contract, all others were awarded to local researchers, whether they are individuals and/or institutions, making it difficult to establish whether multinational corporations and foreign research institutes use other channels to access Colombian biodiversity, such as access to biological resources of border ecosystems. However, contracts of access to genetic resources signed by other Andean countries are exceptional. It seems possible that access to genetic resources and their byproducts was conducted with permits for scientific research on biodiversity as illustrated by the "Global Ocean Sampling Expedition" Case Study in the Galapagos National Park, Ecuador; nonetheless, more information (Nemogá-Soto y Lizarazo Cortés 2013) is required. In this sense, it is clear that the expectation of Decision 391 in relation with bioprospecting countries with developed technology has not been realized since 1996, because in practice, foreign researchers rarely use institutional channels of access and there is no substantial evidence of requests filed in the Andean region.

Studies conducted found that the effectiveness of the procedure to obtain the contract for access to genetic resources is influenced by actions of both, the applicants and the National Competent Authority (NCA) (Nemogá-Soto 2010; Nemogá-Soto and Rojas 2010). On the one hand, the applicant is unaware of the requirements of the application and submits incomplete documentation, causing a delay in the delivery of the certificate of publication of the administrative order that starts the process, and on the other hand, the NCA takes too long to review the application and generate the formal and substantive requirements and issue the initial documents and resolutions.

In Colombia, it is observed that the type of problems in the operation of the access regime system varies. For instance, between 2008 and 2009, the NCA signed 18 contracts and reduced the duration of the proceedings, but between 2010 and 2012 it signed six contracts (PLEBIO 2012). During 2012, the MADS was restructured and the group of access to genetic resources was created, which meant there was: a better understanding of the procedures, of the explanatory guides regarding the process and better communication between applicants and the environmental authority. The case of this country demonstrates that it is national institutions and researchers who bear the cost of compliance with the access regime; and it is clear that national researchers and institutions contribute most of the research with State funding. Similarly, the situation illustrates that neither international bioprospectors nor researchers from other countries cooperate substantially with access regimes and so, it remains uncertain whether they ever will. In this context, one should consider the need to provide facilitated access to national research institutions.

The differential treatment is based on Art. 8 (a) of the Nagoya Protocol, and seeks to promote and encourage non-commercial research for conservation and sustainable use of biodiversity, as well as strengthen the scientific and technological capacities of the countries of origin of the resources. As there are precedents for favorable rules for national researchers, López Cabrera Medaglia and Silva (2008) cite the Philippines, Brazil, Costa Rica, Malaysia and Australia as regimes with exceptions for non-commercial scientific research. To the extent that it pertains to the exercise of sovereign rights on access to genetic resources and traditional knowledge and not to intellectual property rights, the provisions on national treatment under Art. 3 of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) does not strictly apply.

Meanwhile, Art. 6 (3, b) of the Nagoya Protocol seeks to provide non arbitrary and fair standards and procedures, about access to genetic resources. Similarly, Art. 4 of the Nagoya Protocol reaffirms the principle that its validity does not affect the rights and obligations of the parties arising from pre-existing international agreements. In designing and establishing legislative, administrative or policy measures, countries rich in biodiversity may –in the development of their sovereign rights and national interest considerations– encourage the development of non-commercial research and education on ecosystems, creating special conditions for national research on genetic resources considered strategically important.

The exceptional treatment in exercise of the legal faculties which enable access to the countries of origin, can be attained through the criteria of PIC and MAT based on a special and strategic interest (Greiber et al., 2012). Currently, Brazil has a differential treatment on research related to: the evolutionary history of a species or taxonomic group; population genetics; epidemiology studies; DNA collection, germplasm tissues and blood; measurement of the concentration of known substances that indicate disease; relationship, karyotype or DNA testing to determine a specimen; grown commercial varieties of sugarcane and essential oils exploration (Ministério do Meio Ambiente 2006; 2007 a,b,c).

9. Alternatives to promote scientific research

On the basis of the interest of researchers from user countries of biodiversity or megadiverse countries, alternatives have been developed for facilitated access which will leverage scientific research, as it is a means to achieve the objectives of the CBD. In this sense, two contract proposals are examined, which could solve the issue of access to genetic resources.

9.1 Proposed contract template for foreign researchers using biodiversity

Researchers from countries poor in biodiversity are developing a solution for facilitated access to biodiversity *in situ*. In this sense, the Swiss Academy of Natural Sciences (SCNAT) is currently leading the elaboration of an agreement template with model clauses, which can be adapted by countries rich in biodiversity and researchers without commercial interests. In addition, Biber-Klemm and colleagues (2010) suggest that the template can be applied and adapted among providers of genetic resources and researchers, particularly for: biodiversity inventories; systematics; ecology; evolution; identification and isolation of assets, and genetic compounds. The model is based on a bilateral agreement between providers and users, following the premises of Art.15 of the CBD, just contemplating negotiations on access and benefit sharing (Biber-Klemm et al., 2010). In this context, the model is applied on a number of conditions which include:

- i. The resources are accessed by a researcher under the direction and responsibility of a research institution.
- ii. The research is not commercial in nature and its results are available to the public.
- iii. The unexpected results may be susceptible to use in a commercial context.
- iv. The benefits derived are non-monetary as a rule and are generated during the research process.
- v. The genetic resources could be transferred to third parties within the framework of practical cooperation between research institutions.

The proposal identifies the risk that even without commercial intent, both the resources as well as the information accessed and generated under research premises can be exploited by certain initiatives without MAT that cover the distribution of benefits. It is also recognized that the researchers' need for dissemination may conflict with the interest of countries rich in biodiversity to control the use and transfer of resources. In particular, researchers are interested in publishing the results on time, meeting standards of scientific accuracy and sharing biological material and information with colleagues. In this scenario, in issues such as biodiversity inventories and ecological studies, where there is a low probability of results of relevance to the commercial sector, it is suggested that instead of control over the uses, the countries of origin of the resources could require periodic reports on the progress of the research and monitor compliance with the agreements reached.

9.2 Proposed framework contracts for research institutions and centers

In megadiverse countries, fair and equitable benefit sharing remains a valid and enforceable goal, as well as the need to strengthen their endogenous scientific and technological capabilities, proposing solutions that facilitate the compliance with the access regime. So in countries that have access regimes such as Decision 391, the use of framework agreements (FA) stipulated in its Art. 36, has been proposed considering that: "the national competent authority may enter into access contracts with recognized universities, research centers and researchers, to support the execution of various projects in accordance with the provisions of this Decision and in accordance with the national legislation of each member country. "

The option of Art. 36 is based on the need to provide easier access to academic and scientific institutions because they conduct biodiversity research at a country level. In Colombia, for example, the adoption of framework agreements with recognized universities and research institutes would cover at least 97% of the research on genetic diversity (Nemogá-Soto 2010). One advantage to this option is shown in academic and research institutions that become involved as part of the solution, because when they identify and organize their thematic lines or areas within their institutions, they can ensure that their researchers will observe the access regime. Upon defining the lines of research on a framework agreement, institutions may include new projects without starting a new request for access to genetic resources. The process in itself generates a contractual relationship, responsibilities and obligations between the NCA and the beneficiary institution, who pledges to comply with the access regime under pain of administrative and disciplinary sanctions.

Some research projects could generate results of commercial interest. In order to exploit or license the resources, the beneficiary institution must comply with the requirement of the PIC, notifying the NCA and starting the process for establishing a fair and equitable benefit sharing. Some criteria for determining the commercial nature of the proposal are to establish relations with the private sector in order to: conduct research on the potential use or scaling and testing of products; start negotiations for the licensing of research results; determine product offer; obtain a marketing registration and finalize arrangements or agreements for the temporary transfer or sale of research findings.

When a properly designed FA is authorized by the NCA using the access regime, it does not give up its powers but it manages to build relationships of trust with the research institutions, and these in turn acquire clear responsibilities which they must comply with or be sanctioned. In this situation, the additional responsibility that the beneficiary institution acquires is compensated by its strengthening, because having facilitated access turns it into a reference point for international institutions and research centers interested in working with local partners.

The agreement on access to genetic resources and benefit sharing for academic non-commercial research from the SCNAT as well as the proposed FA of the National University of Colombia, meet the articles and model clauses to be adopted according to the needs of stakeholders (Nemogá-Soto 2009; Biber-Klemm et al 2010). The two options are reference points for solutions, because they recognize the sovereignty of countries over their natural resources and the legitimacy of access regimes. Likewise, these can be strengthened by international instruments such as the Nagoya Protocol, enabling partnerships between national and foreign researchers. Equitable participation in the design, implementation and use of research results by researchers from the countries of origin, become the basis for strengthening their endogenous capacities. Framework agreements regarding MAT strengthen trust and transparency with the research objectives, scope and potential uses of biodiversity, laying the foundations of respect for the standards set by the states to enforce fair and equitable benefit sharing.

10. Problems faced by scientific research in the countries of origin

10.1 Case of the Institute of Biotechnology, National University of Colombia

The Biotechnology Institute of the National University of Colombia (UNC) filed a request for access, postulating the project entitled "Isolation and identification of a microorganism of the genus *Lactococcus* sp. as a producer of a natural polymer and exploring its potential industrial and commercial applications". This request was filed as scientific research without commercial interest.

In this specific case in Colombia, the application process and the research project were developed at the same time, advancing to the point of finding results that required a patent application and an evaluation of scaling for biopolymer production, with participation of a private company. The features of this case reveal several problems under the regime for access to genetic resources which are, namely:

- i. The lack of experience and of clear criteria to differentiate between commercial and non-commercial research.
- ii. The excessive duration of the application process, having taken 11 years to be signed as the first commercial contract in the country.
- iii. The requesting institution was sanctioned by environmental authorities for illegal access.
- iv. The patent application was rejected in Colombia, even after being granted other countries.
- v. The patents obtained have not been exploited or licensed.

Some of the milestones in the procedure for obtaining access are: the application was filed in August 2001. The administrative order that started the process was issued in December 2003. The Resolution of acceptance was issued in March 2010, and the access contract was signed in July 2012. Thus, according to Nemogá-Soto and Rojas (2010), the main reasons that influenced the long duration of the process could be summarized in the following points:

- i. Ignorance, on the part of both the environmental authority and the applicant, regarding the rules for access to genetic resources.
- ii. The mismanagement of the environmental authority regarding the development of requirements, technical concepts and administrative acts.
- iii. The incomplete submission of the application and the formulated requirements.
- iv. Changing the request for access to research with commercial purposes during the processing.
- v. The proposed benefit distribution was categorized as unsatisfactory by the NCA.
- vi. The reduced capacity of the NCA to negotiate benefits.

In this case, the UNC was sanctioned for illegal access while conducting scientific research and submitting the respective application, but it later benefited from the single contract awarded in the country for access to genetic resources for industrial application and commercial gain. The processing of this application and its features, allowed the NCA to start building parameters for monetary benefit sharing stemming from the access to genetic resources. In 2007 the UNC submitted a proposal to the NCA for the distribution of economic benefits during contract negotiations for commercial purposes; however, it was not accepted because it did not contain clear monetary figures or proportions. After several years of negotiation, the proposal incorporated into the awarded contract awards monetary benefits related to industrial and commercial property value. In both situations, it is agreed that the MADS will receive 10% of all royalties that the UNC perceives annually.

The application of the UNC was submitted for the purposes of basic research, but during the execution of the research project it went through a transition towards the commercial exploitation of the results, requiring a patent application and agreements with a private company for the potential

industrial use of the biopolymer. We must recognize that the patent does not guarantee neither the exploitation of the invention, nor the licensing or commercialization of research results. Nevertheless, the patent was granted in three European countries. Due to the academic and research vocation of the UNC and the limited funding for public research institutions, private business investment contributed to identify the uses of the biopolymer that might be of interest in the market and to build the pilot plant for production.

The application process often implies incoherent situations which demonstrate the inexperience of the NCA in the effective operation of the access regime, even on the issue of the economic sanctions to the UNC in 2010, citing "the access to a genetic resource to isolate and identify a microorganism belonging to the genus *Lactococcus* sp., and get a naturally occurring biopolymer through its enzymatic activity, for research purposes "(Art. , Res 1459-1410) without having a contract for access to genetic resources. As a basis for imposing the sanction, the NCA considers the patent application as proof of the commercial interest of the project. However, between October 2002 and April 2003, the pending patent was approved within the framework of the access request, because it obtained the export permit for the organism in order to meet the deposit requirement for the patent.

Another contradictory aspect during the process was the fact that in Resolution 1459 of 2010, the NCA argued having insufficient information to make an assessment of the application, and it was its duty to guarantee the right to a healthy environment and comply with the rules of access to genetic resources. In practice, the NCA had to carry on processing the request for access for scientific research purposes, taking into account that the research had no discontinuity. Additionally, the research project did not violate the right to a healthy environment and the UNC initiated the request for access to genetic resources in 2001. Also, the NCA had to comply with the provisions of Decision 391, observing the terms of the procedure provided in the regulations, as well as developing standards that would clarify the process, the scope of the concepts of the various dependencies and the requirements.

Another inconsistency of the NCA in this case was evidenced in March 2006, when the License Department of the MADS informed the IBUN-UCN that it would proceed to prepare the draft of the contract of access for research purposes (Res. 1459 2010), because through Technical Concept No. 1652, of 2008, prepared by the Department of Ecosystems, it was noted that the project was not viable for industrialization and commercialization. This was a repetition of what happened in 2008, when the entity was not conducting commercial activities on the biopolymer. After the beginning of the research through Res. 264 of 2008, the Department of Ecosystems determined that the project was on its research a development stage, which is why a period of time was required before the project could be deemed to be a commercial exploit, (Res. 1459 of 2010). Nowadays, the NCA has begun to guarantee the necessary technical and institutional capacities and it is expected that it will have the staff continuity needed to operate the access regime.

10.2 Case of Bioprospecting in the Galapagos National Park, Ecuador

During 2003 and 2004, a group of researchers led by J. Craig Venter Ph.D., member of the J. Craig Venter Institute (JCVI), conducted the " Global Ocean Sampling Expedition" in the Galapagos National Park, collecting over 150 seawater samples, each of 200-liter collected every 200 miles.

In this case, a Memorandum of Understanding (MOU) between the Institute for Biological Energy Alternatives (IBEA) and Ecuador, was signed establishing the following scope: "Whereas, IBEA is undertaking a global ocean expedition for conducting a scientific research project aimed at studying microbial diversity with the objective of classifying the Galapagos Islands microbial diversity in its coastal waters and terrestrial communities around them."

The project is presented as an activity to increase knowledge of the microorganisms that inhabit the seas and understand how they function in their natural ecosystem, focusing on the study of the effects of humans on the environment and understanding the evolution of life on earth. In the case of Ecuador, the signed MOU says "(...) to determine the complex interplay between groups of microorganisms that affect environmental processes of regional and global importance, conducting sampling from the vessel R.V. Sorcerer II, and applying a genomic approach of total environment (...)" (Ministry of Environment of Ecuador and The Institute for Biological Energy Alternatives, 2004).

With regards to the geographical scope of the research, much of the sampling was carried out in international waters not subject to the rules of national ABS, and another was executed in the territory of 17 countries from different continents and regions: Latin America (Ecuador, Mexico, Panama and Honduras); North America (Canada and USA); Oceania; South Pacific (New Caledonia, French Polynesia and Vanuatu); Africa (Tanzania and Seychelles); Europe and UK (Sea twill and Bermuda).

In relation to the resources the MOU refers to microbial diversity and microorganisms, without specifying amounts or details, which may be partially explained by the fact that these are water samples, but a more complete description is required and may be found in the Collection Permit granted by the Galapagos National Park. Additionally, the MOU does not mention the real or potential uses of the collected resources in detail, it merely mentions –in a general and abstract way – that the samples on which the project is based are useful "(...) to determine the complex interplay between groups of microorganisms that affect environmental processes of regional and global (...) importance."

Within this bioprospecting framework, it must be considered that in 2004 there was evidence that marine organisms are of academic non-commercial interest but have potential for industrial processes. For instance, they may be precursors to extract the useful enzymes for industry as well as for the biofuels industry. Indeed, the IBEA received one million dollars (USD) at the beginning and then an additional four million, as funding for its global ocean sampling expedition (Potagge 2006).

In known contractual agreements, particularly in the "Memorandum of Understanding for Collaboration in Microbial Biodiversity", the term of the agreement is of two years from the date of subscription. This period may be renewed upon mutual agreement by the Parties, expressed a minimum of two months prior to its expiration. In addition, if the parties do not develop a joint Project Plan in a period of one year from the subscription, the MOU will automatically cease without any further obligations.

In the case of the MOU between Ecuador and IBEA, it was specified that clauses 4, 5 and 8 would survive termination and even after the completion deadline. The clauses referred to intellectual property (4), the publication and dissemination of Information (5) and miscellaneous issues (8). In addition, the MOU has no specific provisions devoted to monetary benefits as such, since it includes them in the terminology used in the CBD, when talking about obtaining greater "knowledge" of biodiversity that is useful for "conservation". These commitments are expressed in a rather general and abstract manner.

There are no indicators in the fifth clause pertaining to publication and dissemination of the information, which states:

"In order to make the information available to the global scientific and public communities, the parties specifically agree that the raw genomic data shall be provided only with their express permission. Once the data have been analyzed, all the information shall be deposited in public databases and published in scientific forums, where it shall be acknowledged that the information obtained is part of the genetic patrimony of the state of Ecuador.

The IBEA and the MAE, through the *Parque Nacional Galápagos*, shall jointly collaborate on one or more scientific publications analyzing the genomic data in the manner established in the Project Plans approved by the appropriate authority. The parties agree that scientists from other countries, who are also collaborating in the global sampling expedition, may be acknowledged as coauthors. The MAE, through the *Parque Nacional Galápagos*, agrees to provide cooperation within the scope of its jurisdiction and the applicable legal framework in order to facilitate the objectives of the global sampling expedition in the Galapagos Islands.

The parties shall also work, as appropriate, on joint activities to disseminate and communicate information about and deriving from the collaboration, not only to the scientific community, but also to the public in general, and to educational institutions, particularly those in Ecuador, as long as this information is used solely for scientific, not commercial, purposes."

The first results reported from the Sargazo were disseminated in 2004, in the scientific journal "Science" and most of the remaining findings were published during 2007 in a series of eight articles in the open access journal "PlosBiology", with three of them being classified as research. In the processing of the permit for biodiversity research, the Charles Darwin Research Station, academic and scientific research institution, recommended the approval of the research as this is of great value for a better understanding of the role of marine microorganisms in environmental processes." Additionally, a researcher at the University of Guayaquil presented a report, which partially supported the issuance of the research permit, because he said that the proposal "would increase the scientific, technological and technical capacity at the national level on the way to the conservation of biodiversity and sustainable use of biological resources."

Today, it has been confirmed that none of the articles credited an Ecuadorian researcher listed as coauthor. In the first research article published in "PlosBiology", out of the 34 co-authors: 28 are located in the United States of America; four are residents or are ascribed to Mexican universities; one is a resident or is ascribed to research institutions in Costa Rica, and one is linked to an institution in Chile. In itself, authorship or co-authorship of an article is not something that can be obtained by way of distribution of profits, because it depends on the contribution and effective participation in the project or during the writing of the article. However, the absence of Ecuadorian authors suggests that the project omitted direct benefits, at least in terms of the research training and the transfer or exchange of knowledge or technology. One of the articles contains acknowledgments to staff from Ecuador and other countries, while other articles recognize the sovereignty of countries over the samples, which can hardly be seen as fair and equitable sharing of benefits arising from the utilization of genetic resources.

The situation of the MOU should be analyzed carefully, because when the expedition was conducted, the Bonn Guidelines of 2002 were already in effect, and though they are not binding, they could be considered as a factor in the relationship between the Parties represented by Ecuador and IBEA. At present, scientific publications are in the public domain and genetic information obtained is in two databases, namely: GenBank, managed by the National Institute of Health in the United States of America; and the CAMERA project managed by the University of California, San Diego, and the IJCV, which hosts metagenomic information. Regarding patents or other intellectual property rights (IPR) over genomic DNA and sequenced data, IJCV indicated that these would not be requested. In fact, a preliminary inquiry confirms this. However, there are two patents under obligation to disclose federal funding (Bayh Dole Act), which claim the same sponsorship from the Department of Energy of the United States of America (DOE) because it co-financed the expedition; with documents proving the existence of financial support for two projects: "Global Ocean Sampling Expedition" and "Reconstruction of a Bacterial Genome from DNA Cassettes".

There are two other projects whose research objective has been focused on ecosystems and marine environments. Projects Malaspina from Spain and "Tara Oceans" from France, bear some similarity to the Sorcerer II of the United States of America. The first, conducted between 2010 and 2011, gathered at least 250 researchers, had an investment of 17 million Euros, reported 300 sampling stations, included 21 institutions from different countries, indirectly linked 35 countries in research, and collected 70,000 samples of water, air and plankton (www.expedicionmalaspina.es). The second, was developed with funding of 9 million Euros, visited 32 countries, registered three sampling permit rejections in the national waters of Oman, India and Ecuador (Galapagos Islands), and collected 27,882 samples from 153 sampling stations (<http://oceans.taraexpeditions.org/en/>). The three projects derive some inspiration from both, the endeavor of Charles Darwin on the Beagle, and on the HMS Challenger. According to some analysts, the analogy is used as a marketing or self-promoting tool, or as an instrumental strategy because it serves as a defense against possible accusations under the premise: "If it's in the Darwin school of Biopiracy, then fine" (Nicholls 2007: 383).

When contrasting the statements of J. Craig Venter on the alleged non-profit nature of the expedition with those of the Director of the DOE, and referring to the motivations for financing the project, Matthew Rimmer (2009), professor at the National University of Australia, suggests that the investment of the DOE assumes that the Sorcerer II Expedition was intended to be more than an exercise in basic science. The scientist states that: "The Institute sought to explore energy solutions for environmental problems such as global warming and find new biological sources of cleaner and more efficient fuels, including hydrogen. As such, there was an underlying motivation when carrying out research on microorganisms with the prospect of achieving commercially useful results" (Rimmer 2009).

A final aspect to highlight is the intervention of international diplomacy, since this case was presented in the media as scientific research, with the J. Craig Venter team mentioning that it had support from the DOE to get research and collection permits in the countries where samples were obtained: "In accordance with national laws and international treaties, and under the guidance of the State Department of the United States of America, IBEA obtains permits for research and sampling from each country in which samples will be collected" (Rimmer 2009). The oceanic expedition was no stranger to controversy, such as the one arising when the French government opposed sampling in their Polynesia. However, the authorization was granted when the government of United States of America moved its political influences (Rimmer 2009).

The analysis of the case studies mentioned above proves or at least suggests that –in addition to being technical and legal issues– scientific research, access and benefit sharing are also permeated by power relations as well as by media and political influence. In contrast, the French expedition "Tara Oceans" that years later tried to sample in the Galapagos Islands as part of a global marine research project, gave up and argued that it was more than a year of negotiations with no response to its request for permission research. So, one reason is perhaps a weaker political influence of the French government in these matters; and the other might be that as a result of the experience of the Sorcerer II expedition, the process of collection permits for foreigners has become stricter in Ecuador.

11. Final Considerations

This analysis argues that the characterization of diverse countries as suppliers and the operative capacity of access regimes are considered as unexpected effects against the strengthening of endogenous scientific and technological capacities. The negotiations under the framework of the CBD, identifying countries of origin of resources as suppliers only downplays the processes that enable the gradual formation of scientific and technological capabilities. It also belittles the generation of knowledge and diverse varieties of biodiversity that enrich agriculture and food as a result of the innovations and practices of indigenous peoples and local communities. Meanwhile, access regimes designed with the expectation of partaking in the economic benefits derived from the use of genetic resources also have an unexpected consequence: making genetic research conducted by national researchers illegal due to imposing parameters designed for industrial and international bioprospectors.

The possible solutions examined should facilitate access to research on biological and genetic diversity, while recognizing the rights of countries of origin and ensuring the benefit sharing arising from their use. For this reason, emphasis is placed on applying an approach that guarantees the conduction of research with facilitated access through framework agreements, as one of the options, while recognizing the potential to identify genetic material and byproducts of industrial and technological application.

Some measures which can be pointed out in the management of access regimes and which safeguard the objectives of the CBD, become a temporary option that may provide flexibility given the current situation and strengthen national research. For instance, research projects financed with state resources should start and advance while applications are being processed. Likewise, when an agreement regarding benefit sharing is established in advance at the time access to genetic resources for commercial purposes is granted, options should be designed so as not to restrict the use of the material and research results for public purposes or developments that generate benefits for the country. Particularly when a research process in biological and genetic diversity is embedded in value chains and innovation sequences, a facilitated access approach must recognize the continuity between research, innovation and development. Also, its mechanisms must encourage researchers to report any possible commercial potential for the implementation of projects.

Some points raised by previous studies on access in the region are confirmed in this analysis, suggesting the importance of flexible treatment for scientific purposes in the context of a comprehensive ABS regulatory system. Thus, user countries can establish measures regarding a possible commercial use of genetic resources, allowing the country of origin to know if such use existed in order to exercise their rights in foreign jurisdiction in case there is a breach of the established conditions (López Cabrera Medaglia and Silva 2008).

The experiences of the region, such as the case of Colombia suggest that access regime designs and their regulations must prioritize the strengthening of the endogenous scientific and technological capacities without expecting any monetary benefit from the industrial application of genetic resources. In this regard, the experience of Costa Rica should be considered given the fact that the National Biodiversity Institute (INBio) prioritizes the improvement of their scientific and technological capabilities as well as programs for conservation and sustainable use of biodiversity.

National research programs involving research institutions and universities which are the beneficiaries of an access framework agreement, become a technology platform for access to genetic resources, research groups and training in advanced technology in the countries of origin. They also contribute in the exercise of their rights to biodiversity. With this perspective, a broad spectrum of possibilities for international cooperation emerge when attracting research centers and universities with the largest scientific progress in different scientific areas. Cases of countries that have progressed in terms of their endogenous capacities, such as Brazil, Costa Rica and Cuba, may be seen as experiences and alternatives to promote collaborative programs that facilitate access to biodiversity.

In terms of political decision, access regimes and their regulations should include appropriate provisions to recognize the value and relevance of the collections of organisms, tissues and genetic material. Similarly, national DNA banks should be established as they are strategic and work as reservoirs for research on biological and genetic diversity. The evaluation of this objective is of the utmost importance when including clauses into access contracts pertaining to sample destruction once the research project is concluded.

Another situation concerning researchers from countries poor in biodiversity and those found in the countries of origin of genetic resources, can be evidenced in the emphasis placed on requesting differential treatment for research; but at the same time, there are models that show efforts to strengthen local capacities. In addition, it is pertinent to refer to political decisions regarding schemes for the dissemination of results which are promoted from the perspective of scientific interest, but there is not a single model as of yet. Dissemination schemes of genetic data based on open and free criteria, do not prevent biopiracy situations *per se*. Although making the information available and including it in the technical status may reduce or prevent the possibility of obtaining patents, access to this information is public and anyone who gains access to it may file for a patent if it modifies, transforms or combines the information.

The availability of public information in some cases allows the establishment of business models, combining intellectual property rights and services based on databases repositories of free access. When deciding on access regulations or contracts pertaining to models of dissemination of

results, the standardization and adoption of a single model as the most appropriate should be avoided. In practice, everyone has potential and limits, advantages and disadvantages and, therefore, a case-by-case analysis is required using intellectual property criteria and articulating models of dissemination of results with various business schemes. A final point concerns patent applications which in themselves do not imply Biopiracy, because they could be validating truly innovative products and procedures developed from genetic resources and/or products, meeting the requirements of PIC and MAT.

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