



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

Regional GEF Project “Strengthening the Implementation of Regimes of Access to Genetic Resources and Benefit Sharing in Latin America and the Caribbean” executed by the Regional Office for South of the International Union for Conservation of Nature (IUCN South America) and implemented by the Regional Office for Latin America and the Caribbean of the United Nations Environment Programme (UNEP-ROLAC).

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1. Biology 2. Genetic Resources 3. Indigenous worldview 4. Latin America 5. Caribbean

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Abbreviations and acronyms

(* Acronym has been kept in original Spanish form)

ABS	Access and Benefit Sharing of genetic resources
ACTO	Amazon Cooperation treaty Organization
IDB	Inter-American Development Bank
BfN	Bundesamt für Naturschutz
CAF	Andean Development Corporation *
CAN	Andean Community of Nations *
CBD	Convention on Biological Diversity
CENIBIOT	National Center for. Biotechnology Research *
DNA	Deoxyribonucleic acid
ECLAC	Economic Commission for Latin America and the Caribbean
CIDEM	Drug Research and Development Center *
CINPE	International Centre of Economic Policy *
CNB	National Commission against Biopiracy *
COLCIENCIAS	Colombian Institute for the Development of Science and Technology*
CONAP	Confederation of Amazonian Nationalities of Peru *
CONICIT	National Council for Technological and Scientific Research *
CONPES	National Economic and Social Policy Council *
CONCYTEC	National Council for Science, Technology and Technological Innovation *
DOE	U.S. Department of Energy
FA	Framework agreements
FAO	Food and Agriculture Organization of the United Nations
FDPI	Indigenous Peoples Development Fund *
FSC	Forest Stewardship Council
GAP	Good Agricultural Practices
GCUJTL	<i>Jorge Tadeo Lozano</i> Consulting Group of the University of Bogota *
GEBIX	Colombian Center for Genomics and Bioinformatics of Extreme Environment
GEF	Global Environmental Fund
GIIB	Group of Research and Innovation in BioTrade *
GTPI	Working Group on Indigenous Peoples *
IAVH	Alexander von Humboldt Institute *
IBEA	Institute for Biological Energy Alternatives
ICBG	International Cooperative Biodiversity Group
IES	Institute of Ecology and Systematics
IGC	Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore
IIAP	Peruvian Amazon Research Institute *
IJCV	J. Craig Venter Institute *
ILO	International Labour Organization
INBio	National Biodiversity Institute of Costa Rica*
INDECOPI	National Institute for the Defense of Competition and the Protection of Intellectual Property *
INE	National Statistics Institute *
INSDC	International Nucleotide Sequence Database Collaboration
IPE	Peruvian Economy Institute *
IPR	Intellectual Property Rights
IUCN	International Union for Conservation of Nature

KRIBB	Korean Research Institute of Bioscience and Biotechnology
LAC	Latin America and the Caribbean
MADS	Ministry of Environment and Sustainable Development *
MAE	Ministry of Environment of Ecuador *
MAT	Mutually agreed terms
MAVDT	Ministry of Environment, Housing and Territorial Development *
MIF	Multilateral Investment Fund
MINAE	Ministry of Environment and Energy *
MINAM	Ministry of Environment *
MINCER	Ministry of Foreign Trade *
MMV	Medicine for Malaria Venture
MTA	Material transfer agreement *
MU	Memorandum of understanding
NCA	National Competent Authority
NCDDG	National Cooperative Drugs Discovery Group
NIH	National Institutes of Health
OAS	Organization of American States
OCPI	Cuban Industrial Property Office *
PAB	Andean Biotrade Programme *
PCT	Patent Cooperation Treaty
PNPB	National Program for Promotion of Biotrade *
PBD	<i>Peru Biodiverso</i> Project *
PFC	Pharmaceutical, food and cosmetic sectors
PIC	Prior Informed Consent
RMIB-LAC	Indigenous Women's Network on Biodiversity of Latin America and the Caribbean *
RNA	Ribonucleic acid
SAU	Strategic Action Unit
SCNAT	Swiss Academy of Sciences
SINAC	National System of Conservation Areas *
SINCHI	Amazonian Institute of Scientific Research *
SGCAN	General Secretariat of the Andean Community of Nations *
SIICEX	Integrated Foreign Trade Information System *
SIRIAP	Regional System for the Peruvian Amazon *
SEDEFA	Ecuadorian Society of Forest and Environmental Law*
SME	Small and medium enterprises *
SPDA	Peruvian Society for Environmental Law *
TEBI	The European Bioinformatics Institute
TEEB	The Economics of Ecosystems and Biodiversity
TRIPS	Trade Related Aspects of Intellectual Property Rights
UN	United Nations
UNC	National University of Colombia *
UNEP	United Nations Environment Programme
UNCTAD	United Nations Conference on Trade and Development
Unimedios	Media Unit *
UNDP	United Nations Development Programme
UNDRIP	UN Declaration on the Rights of Indigenous Peoples
USPTO	United States Patent and Trademark Office
WIPO	World Intellectual Property Organization
WTO	World Trade Organization

Presentación

El Proyecto Regional "Fortalecimiento de la Implementación de los Regímenes de Acceso a los Recursos Genéticos y Distribución de Beneficios (ABS) en América Latina y el Caribe" (Proyecto Regional-UICN-PNUMA/GEF-ABS-LAC), apoyado por el Fondo para el Medio Ambiente Mundial (sigla en inglés GEF) es una iniciativa ejecutada por la Unión Internacional para la Conservación de la Naturaleza (UICN) e implementada por el Programa de las Naciones Unidas para el Medio Ambiente (PNUMA), en coordinación con el Convenio sobre la Diversidad Biológica (CDB), que tiene como objetivo el fortalecer capacidades para el desarrollo e implementación de regímenes de ABS en la región.

El proyecto es complementado por otras dos iniciativas regionales sobre ABS apoyadas por el GEF en África y Asia, porque conjuntamente buscan promover un mejor entendimiento del tercer objetivo del CDB sobre acceso a los recursos genéticos y la distribución justa y equitativa en los beneficios derivados de su uso. Estos proyectos, se encuentran apoyando el marco de trabajo del Protocolo de Nagoya sobre ABS, adoptado en el 2010, así como a la Meta de Aichi 16 del Plan Estratégico para la Biodiversidad 2011-2020.

Durante el Proyecto Regional-UICN-PNUMA/GEF-ABS-LAC se han desarrollado una serie de herramientas prácticas para mejorar las capacidades en el tema de ABS, siendo a través del compartir de experiencias y lecciones aprendidas. Las publicaciones han sido preparadas a partir del conocimiento de varios expertos, provenientes de las autoridades nacionales y regionales, comunidades locales y pueblos indígenas, investigadores, académicos y sector privado, entre otros. Así, se espera una extensa disseminación de los resultados a una amplia gama de actores relevantes en la región de América Latina y el Caribe.

Quisiéramos agradecer a los involucrados en este esfuerzo regional, incluidas las Autoridades y Puntos Focales Nacionales de los ocho países participantes (Colombia, Costa Rica, Cuba, Ecuador, Guyana, Panamá, Perú y República Dominicana), la Organización Mundial de la Propiedad Intelectual (OMPI), así como otras instituciones y expertos que se han unido a este proceso, compartiendo su conocimiento en miras a contribuir al mejor entendimiento sobre este tema fundamental.

Estamos seguros de que las herramientas prácticas desarrolladas en este proyecto regional apoyarán a los países que se encuentran implementando el Protocolo de Nagoya, así como a la Meta 16 de Aichi para la Biodiversidad. Finalmente, quisiéramos alentar la lectura de estas publicaciones, así como la visita al portal del proyecto (www.adb.portalces.org), donde se podrá encontrar información clave recogida durante el proceso.



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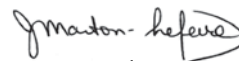
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Presentación

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Foreword

The Regional Project "Strengthening the implementation of Access and Benefit Sharing (ABS) regimes in Latin America and the Caribbean" (Regional Project-ABS-LAC), supported by the Global Environment Facility (GEF) is an initiative executed by the International Union for Conservation of Nature (IUCN) and implemented by the United Nations Environment Programme (UNEP), in coordination with the Convention on Biological Diversity (CBD), to strengthen capacities for the development and implementation of ABS regimes in the region.

This regional project is complemented by two other GEF supported regional projects on ABS in the Asia and Africa regions. Together, these projects aim to promote a better understanding of the third objective of the CBD on access to genetic resources and the sharing of benefits derived from their use. The projects are furthermore in support of the framework of the Nagoya Protocol on ABS, adopted in 2010 and Aichi Target 16 of the Strategic Plan for Biodiversity 2011-2020.

A series of practical tools have been developed by the Regional Project-ABS-LAC to improve capacities in the field of ABS through the sharing of experiences and lessons learned. These publications have been assembled from the knowledge of a range of experts (national and regional authorities, indigenous and local communities, researchers, academia and private sector, between others). Extensive dissemination to a broad range of relevant stakeholders in the Latin American and Caribbean region is planned.

We want to thank all those involved in this regional endeavor, including the Authorities and National Focal Points of the eight participating countries (Colombia, Costa Rica, Cuba, Dominican Republic, Ecuador, Guyana, Panama and Peru), the World Intellectual Property Organization (WIPO), as well as organizations and experts who have joined this process for sharing their knowledge in the expectation that it will contribute to a solid base for a better understanding of this fundamental topic.

We are confident that the practical tools developed in this regional project help countries implementing the Nagoya Protocol and help achieving Aichi Biodiversity Targets 16. We encourage use of these publications and visits to the project website (www.adb.portalces.org), where key information, collected throughout this process, will be found.



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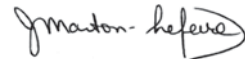
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Improving capabilities through the exchange of experiences is one of the main objectives of the Regional Project IUCN-UNEP-GEF "Strengthening the Implementation of Access and Benefit Sharing Regimes in Latin America and the Caribbean" also known as the IUCN-UNEP/GEF-ABS-LAC Regional Project, which has been portrayed in a series of four publications which analyze critical issues related with ABS and aim at sharing this knowledge with the diverse stakeholders in the region. In this second publication, several case studies that illustrate the interrelationship between research, marketing and the indigenous worldview of biodiversity are analyzed.

In the Latin American scenario, one can observe how the objective of the project evolves in its implementation from its inception to the present. Currently, the Project has been adopted by the Nagoya Protocol, a decision made during the COP10 of the Convention on Biological Diversity (CBD) which not only internationally regulates the issue of access to genetic resources and their equitable distribution, but also ratifies each country's national sovereignty to manage them through legislation.

The IUCN-UNEP/GEF-ABS-LAC Project is conducted within a context of adaptation, expecting that the issue of ABS regimes may converge with a future ratification of the Nagoya Protocol –and objective set for the year 2015 according to the Aichi Target 16 for Biodiversity adopted in the COP10 of the CBD. Meanwhile, the Project responds to the need for improving the capacities in the region, exchanging experiences among the eight countries involved in this initiative and hoping to promote the interest of all the countries in the region.

Within this unique framework of Access and of Benefit Sharing derived from the use of Genetic Resources (ABS), it becomes a priority to emphasize that in recent years, the region known as Latin America and the Caribbean has become a key player on the international scene. The region stands out, both for the development of national and regional regulations on the subject, as well as for the ability to negotiate with the Nagoya Protocol.

The significance attained by regional developments linking the various actors through the analysis of three issues of great interest to the region in this publication, namely: scientific research and its relationship to ABS; and the market opportunities and challenges which genetic resources and the indigenous worldview about biodiversity offer. Analyses are conducted by work teams led by doctors Jorge Cabrera Medaglia of Costa Rica and Ricardo Gabriel Nemogá-Soto of Colombia, as international experts who collaborate with the project and interact with national focal points to improve process capabilities.

The first chapter focuses on scientific research related to the non-monetary benefits of ABS, with the experience of the Project showing that it is still necessary to improve dialogue and the practical mechanisms among national environmental authorities and university researchers, research centers and research institutes, among others. Thus, it is expected for the first actors to understand the needs of the scientific community regarding research, and for the latter to understand the benefits of ABS systems and stop perceiving them as a barrier to the advancement of science.

The second chapter focuses on genetic resources, looking at monetary versus non-monetary benefits, since the latter are often more valuable than those available in the market. In the Latin American context, the experience during the project evidences the difficulty in separating the genetic resource from the biological one, especially when applying a fair distribution of benefits, for example through biotrade initiatives implemented in the region.

The third chapter focuses on topics related to the viewpoints of the various stakeholders, since it is necessary to understand the access to genetic resources and benefit sharing from the perspective of the groups of more direct users, such as indigenous peoples. It is important to consider the communication of indigenous peoples and local communities with environmental authorities and researchers, because this approach actually promotes the construction of a true dialogue where the diverse knowledge about genetic resources is respected.

In this context, which is unique due to the multiplicity of stakeholders, we invite you to continue the discussion on this important issue for the Latin American and Caribbean Region, learning more on the subject from this publication. Likewise, we hope this process will consolidate National and Regional ABS Systems, since it will help them face the challenge of conservation and sustainable use of genetic resources from a stronger standpoint.

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



Tiputini Biodiversity Station, Universidad San Francisco de Quito, © David Romo.

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BIENVENIDOS

TIPUTINI

UNIVERSIDAD SAHMERIANA

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.

Nemogá-Soto G.R.; Rojas Díaz, D.A. and Lizarazo Cortés, O.A. 2014 Biodiversity research in megadiverse countries: strategies for scientific and technical alliances. In: Rios, M. y Mora, A. (Eds.), Access to Genetic Resources in Latin America and the Caribbean: Research, Commercialization and Indigenous worldview. IUCN-UNEP/GEF-ABS-LAC. Quito, Ecuador. Pp. 13-42.

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 Jungcort 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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Commercialization of biodiversity:
markets for genetic resources and biochemical products



Vegetable dyes at Písaq Market, Peru, ©Stephanie Achard.

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Commercialization of biodiversity: markets for genetic resources and biochemical products

1. Introduction

This study analyzes the general data of the global market for genetic resources and biochemicals, as well as studies and opportunities identified at a national level in some countries of Latin America and the Caribbean. It is important to note that despite the significance assigned to genetic resources by developing countries, their specific information on market opportunities for genetic resources and biochemicals is categorized as scarce. On several occasions, the documentation related to biological resources and biotechnology is so general with respect to trade, that it is not even possible to clearly infer their application to specific cases of genetic resources.

In this context, when the focus on biological resources is analyzed through the approximations of their potential market, it becomes a difficult task to distinguish the corresponding genetic resources, creating uncertainty regarding key aspects within regulatory frameworks such as the application of a fair and equitable sharing of derived benefits. Also, concerning bioprospecting cases pertaining to traditional knowledge, uncertainty is even greater and can have an impact on initiatives for a sustainable use of biodiversity.

Today, still identify a large number of reports and documents that are more concerned with markets for biological resources (Biotrade), without specifying the specific sub-sector of use of genetic resources and/or biochemicals with their associated traditional knowledge. Likewise, further studies in this area in order to gain better understanding are needed, like the one conducted by Kerry Ten Kate and Sarah Laird (1999), as well as the one by Sarah Laird and Wynberg Rache (2008). The latter was prepared for the Secretariat of the Convention on Biological Diversity (CBD).

In outlining a global overview of the market for genetic resources and biochemicals, global data is required regarding its economic value. In itself, the calculations to approximate the monetary potential must be associated with a series of commercial activities targeting different niche markets. In order to cover the entire value chain it is necessary to have institutions, policies, legislation, and public investment.

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2. Global market for genetic resources and biochemical products

Generally speaking, the term biotrade means "all the activities of collection and/or production, processing and marketing of goods and services derived from native biodiversity (genetic resources, species and ecosystems) under criteria of environmental, social and economic sustainability" (UNCTAD, 2012: 3). Biotrade products include: organic production, environmentally friendly agriculture and industry, ecotourism, sustainable use of genetic resources, enhancement of technology innovation to prevent or reduce environmental impacts and environmental services inspired by preserving nature, promoting the development of local communities and reducing air, water and soil pollution (Figure 1).

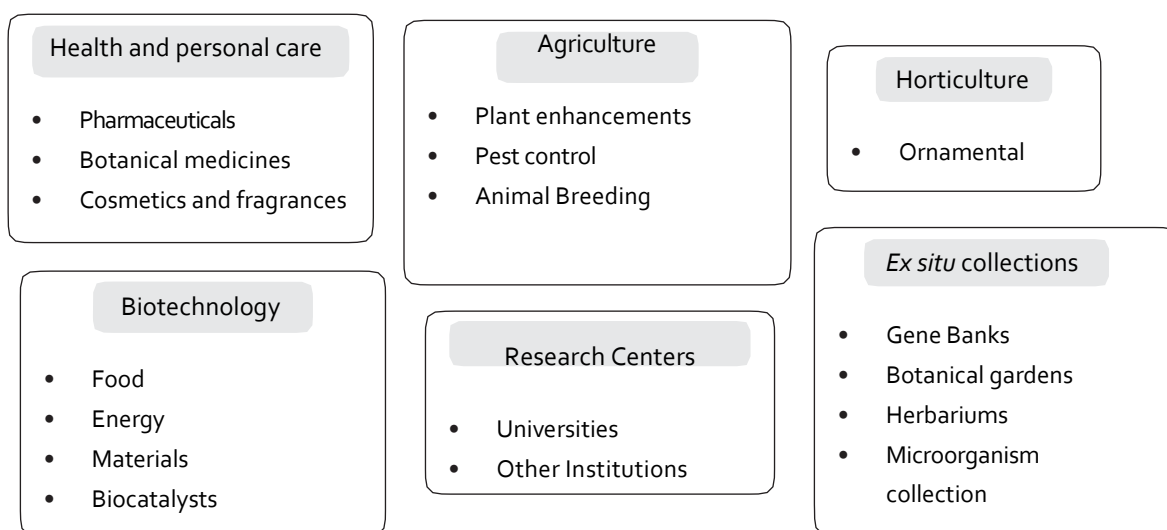


Figure 1. Potential areas for the use of genetic resources and associated traditional knowledge. Source: Holm-Müller, Richerzhagen and Täuber 2005.

With regards to the economic potential of international markets, it is aimed at certain areas or sectors, such as: are pharmaceuticals, biotechnology and crop protection, because the final products are developed from research on genetic resources and biochemical activity (Table 1). Also, some actions of companies in exploration and development, often employ strategies

...such as combinatorial chemistry which does not use biodiversity.

In the case of seeds and horticulture, their very nature requires the use of genetic resources to achieve its commercialization, with their materials coming from *ex situ* kept in collections in the companies themselves *in situ*. Certainly the value of this sector is lower compared to pharmaceuticals and biotechnology. Another niche of interest is that of cosmetic and personal care products because they require less investment in research and development or in approval processes stipulated by regulatory frameworks. Thus, the relation between the genetic resource and the final product is more visible.

Table 1. Global market potential for sectors that use genetic resources.

Sector	Size of the market (2006)	Comment
Pharmaceutics	US\$ 643 billion	A high percentage comes from genetic resources, for instance, 47% of medicines for cancer in the period of 1981-2006
Biotechnology	US\$ 70 billion	Many byproducts coming from genetic resources, such as microorganisms and enzymes, among others
Crop Protection	US\$ 30 billion	Some byproducts from the use of genetic resources
Seeds	US\$ 30 billion	All byproducts from the use of genetic resources
Ornamental Horticulture	Amount of global imports US\$ 14 billion	All byproducts from the use of genetic resources
Personal care, botanical medicines, food and beverages	US\$ 22 billion for herbal supplements US\$ 12 billion for personal care US\$ 31 billion for food products	Some byproducts from the use of genetic resources

Source: Markandya and Nunes 2011.

(A billion corresponds to a thousand million US dollars.)

Recent initiatives from the United Nations Environment Programme (UNEP) on the topic of green economy, are projected in a future renovation of bioeconomics and biotrade with specific processes of interest to the economics of biodiversity. Firstly, there are the conclusions of the Study of The Economics of Ecosystems and Biodiversity (TEEB), coordinated by UNEP and presented in 2010. These conclusions propose concepts for understanding the links between the economy and ecology, emphasizing the relationship of biodiversity and ecosystem services with human welfare, including economic costs associated with the loss of it or inaction to stop such loss, which is illustrated by various studies (<http://www.teebweb.org>). Secondly, the Green Economy initiative –also promoted by UNEP– is shown and is closely related to the economic potential for biodiversity use.

In June 2012, by mandate of the General Assembly of the United Nations (UN) the Rio +20 Conference was held in Rio de Janeiro. The event coincided with the 20th anniversary of the Summit on Environment and Development, or Earth Summit held in this city in 1992. The Conference focused on renewing political support for sustainable development, assessing the progress made so far, analyzing gaps in the implementation of the results of other summits and forums on this subject, as a way of addressing new and emerging challenges. The two key topics of the meeting focused on the green economy within the context of sustainable development and poverty alleviation.

The topic of green economy has been promoted as an initiative by the UNEP since a few years back and has acquired an international standing, since it recognizes the environmental impacts of different development models and their socioeconomic implications. It also promotes a sustainable economic model, including low-carbon income and production processes that respect and protect the environment as opportunities for sectors related to a sustainable use of biodiversity and includes genetic resources. Some facts about the market opportunities for products derived from biodiversity and ecosystem services belong to the TEEB study, being only partially applicable to the case of genetic resources and biochemicals, especially under the category of bioprospecting.

Table 2. Worldwide emerging markets for biodiversity and ecosystem services.

Market Opportunities	Market size in million dollars (US\$) per year		
	2008	Projection 2020	Projection 2050
Certified agricultural products, for example, ecological products	40.000 2,5% of the worldwide food and beverage market	210.000	900.000
Certified forest products, such as the Forest Stewardship Council (FSC)	5.000 Products with FSC certification	15.000	50.000
Forest bio-carbon offsets, for example CDM, VCS and REDD+	21 (2006)	Over 10.000	Over 100.000
Payments for ecosystem services related to water (government)	5.200	6.000	20.000
Payments for watershed management (voluntary)	5 Pilot programs in Costa Rica and Ecuador	2.000	10.000
Other payments for ecosystem services, funded by the government	3.000	7.000	15.000
Mandatory biodiversity offsets, such mitigation banks in the United States of America	3.400	10.000	20.000
Voluntary biodiversity offsets	17	100	400
Bioprospecting contracts	30	100	500
Private land trusts and conservation easements, for example, in the United States of America and Australia	8.000 Only in the United States of America	20.000	Hard to predict

Source: Kumar 2010.

Some economic data submitted by Sarah Laird and Rachel Wynberg (2008) in their study, are projected into four sectors with the following information:

- i. The pharmaceutical industry is characterized by monetary returns above \$500 billion USD per year, with a significant investment in the area of research and development, even though this component is limited to natural products for several reasons. Also, there is an interest of large firms in microorganisms and marine organisms (Jiménez, pers. com. 2013) , but it is decreasing because now their actions are directed to gaining access to genetic resources and biochemicals that are used by intermediaries, such as small businesses and universities, who usually sign contracts with large companies.
- ii. The biotech industry makes over \$54 billion USD in profits, it is made up of a variety of small and medium enterprises (SMEs) (Laird and Wynberg 2008) and invest considerably in research and development. Their technological advances gradually allows for an improvement in the use of genetic resources, incorporating techniques bioinformatics, genomics, metagenomics, proteomics, and other techniques. Generally, resources associated microorganisms are used, especially those typical of extreme environments, and enzymes. Sometimes, this industry requires traditional knowledge as the starting point, because it is grounded on the scientific information about properties, characteristics and potential application of genetic resources, rather than on their ancestral uses.
- iii. The industry of genetic enhancement, particularly vegetable genetic enhancement, has reduced its use of wild genetic resources, but the situation may change due to climate change scenarios; as well as due to the need to increase the genetic pool in order to enhance it with research on collected and preserved ex situ resources. Regarding crop protection and identification of new chemicals or genes, this is becoming an area of growing interest for companies involved in the marketing of these types of products.
- iv. In the market for dietary supplements, personal care products, functional foods and cosmetics, there has been a significant increase in economic value, accounting for \$21.8 billion USD for supplements derived from plants, \$31.4 billion USD for functional foods, and \$12.5 billion USD for cosmetics and personal care or household products.

The Andean region has data which is focused on the market potential for genetic resources, including the subareas that are close to the estimates. So, an example is the study of the Andean Development Corporation (CAF) that defines sectors under criteria such as market size, potential opportunities for value-added activities and to technological or institutional requirements for entry (Quezada et al. 2005). Selected areas and subareas are the result of a development approach from biotechnology and bioinformatics, providing results on the areas of biopharmaceuticals, bioconductors and recombinant proteins against monoclonal antibodies. Data for medicinal plants is not reflected, but that of functional foods is included.

There are two different product markets in the area of cosmetics, one is for the protection of the skin and one for anti-aging. Furthermore, cosmeceuticals are included emerging from trends for a sustainable and ethical consumption of natural products. However, data must be taken with caution since each study reports market estimates in USD dollars for nutritional products whose consistency it

is difficult to determine. For example, the CAF reports a global market for functional foods of \$9,600 million USD in 2008. Additionally, two Peruvian species are estimated to have a value of \$ 77 890 million USD worldwide and of \$ 26,660 million USD for U.S. trade (Hughes 2007). Other assessments examined are derived from a publication by the "Biotechnology Center of Excellence Corporation" in 2003 (Table 3).

Table 3. Facts about the International market for genetic resources by area and subarea of application.

Area of application	Subarea of application	International Market in millions of dollars *
Biopharmaceutics	Recombinant proteins	USD \$ 41,000
	Monoclonal antibodies	USD \$ 57,000 (estimate in 2010)
Herbal medicine and medicinal plants	No data	No data
Herbal medicine and nutraceuticals (natural ingredients for food and beverages)	Functional foods	USD \$ 9,600 (estimate in 2008)
Cosmeceuticals (cosmetics and personal care products derived from botanical extracts)	Skin protection	USD \$ 10,000
	Aging prevention	USD \$ 2,900 (estimate in 2005)
Enzymes for industry, food or related products	Enzymes	USD \$ 22,000
		USD \$ 1,800 (industry enzymes 1988)
Products for agriculture and forestry	Transgenic seed	USD \$ 833 (food enzymes)
		USD \$ 4,000 (estimate in 2004)
Bioinformatics	Genomic bioinformatics	USD \$ 1,100
Bioconductors and microarrays	DNA conductors	USD \$ 397 (estimate in 2000)

Source: Information partially based on the study conducted by the "Biotechnology Center of Excellence Corporation" 2003, quoted in Quezada et al. 2005: 37.

* International market values are estimated for various years according to the report of the CAF and its data (Quezada et al. 2005).

In the general context of biodiversity trade, some countries base their data on secondary sources from other countries. One example is a document from Peru about formulating strategies for biotrade, which has information about the market potential for natural products. In this case, while establishing the Agenda for Peru from 2012 to 2021, the Group for Research and Innovation in Biotrade (GILB) refers to the market for natural products of the United States of America, citing in particular the International Trade Center that emphasizes the trade potential for dietary supplements, functional foods and cosmetics and pharmaceuticals of natural origin.

3. Biotrade Opportunities in Latin America and the Caribbean: case studies in Costa Rica, Cuba, Colombia, Ecuador and Peru

This research describes the situation of the countries or regions where it is possible to locate or identify information on national or regional market opportunities from a perspective that is different to that of the global context. For this reason, the scenario shows countries in Central America and the Caribbean, such as Costa Rica and Cuba; as well as in the Andean region, represented by Colombia, Ecuador and Peru. It is worth pointing out that in the case of Panama and the Dominican Republic, members of two State institutions indicated that there are no specific studies about commercial opportunities arising from the use of genetic and biochemical resources (Hernández, pers. com. 2013; Luque, pers. com. 2013).

3.1 Case Study in Costa Rica

Regarding Costa Rica, relevant information on the biodiversity of the country, both in terms of bioprospecting and conservation efforts, as well as opportunities for sustainable and economic use is presented, with INBio explaining experiences of commercialization of genetic resources and associated traditional knowledge. The Institute is organized into Strategic Action Units (SAU) active in five major thematic areas, with one of them being Bioprospecting. This area is dedicated to research on the sustainable use of genetic resources and biochemicals from biodiversity (Cabrera Medaglia 2013).

Most of INBio's activities are developed in partnership with academic institutions and other research centers. In the case of bioprospecting, INBio has more than 50 agreements with industry and academia, because such agreements allow it to acquire extensive experience in executing projects involving high technology, laboratory equipment and training for their staff, all of which are important achievements of the North- South cooperation established on the basis of signed agreements. An example of the market potential for genetic resources is in the collaborative research and commercialization of phytomedicines conducted by INBio and Business Lisan (Table 1). When referring to bioprospecting, it is defined as " the systematic search, classification and research of new sources of chemical compounds, genes, proteins, microorganisms and other products found in biodiversity and which have potential or current value, for commercial purposes " (Cabrera Medaglia 2013).

Table 1. Partnership between INBio and Lisan for research and marketing of phytomedicines.

With funding from the Inter-American Development Bank's Multilateral Investment Fund (MIF), the National Biodiversity Institute of Costa Rica (a non-profit non-governmental organization) implemented a program aimed at promoting the sustainable use of biodiversity by marketing products made from it, especially through small businesses. With financial support from the program, which includes counterparts of the Institute and of companies, the department of generic pharmaceuticals of the firm *Laboratorios Lisan* and INBio are carrying out a collaborative research agreement for the development of natural products derived from plants (herbal medicines). This has enabled the company to launch their "*Lisan Natura*" product line, giving it an advantage over local competitors that produce generic medicines and natural products without adequate quality control. As part of the collaboration six products have been developed and registered.

In this case, INBio contributed its expertise and experience in the extraction and chemical classification of plants, mostly as a result from the collaboration with international pharmaceutical firms while Lisan contributed with its experience in quality control, product development and marketing. _ A confidentiality agreement was signed initially, which allowed the start of the negotiations leading to the presentation of a research plan by the executing agency and its advisory committee, and the subsequent signing of the aforementioned collaborative research. The partnership covered four main phases: administration, research, knowledge transfer and pre-commercial development. Thus, among the results obtained to this date, we can mention:

- i. Publication of a comprehensive manual of laboratory procedures, including protocols for extraction and standardization.
- ii. Generation of preclinical and clinical data.
- iii. Business and research relationship between a research institution and a small business.
- iv. Provision of materials that meet standards of Good Agricultural Practices (GAP).
- v. Production of six types of products that include a gel, tablets while creams with various therapeutic effects.
- vi. *Laboratorios Lisan* received an award for innovation in 2003

Experience demonstrated that it is possible to generate partnerships between the research sector and the productive sector which translate into commercial products while conserving biodiversity and promoting economic development. It also shows that it is feasible, through partnerships between sectors, to transform knowledge into commercial products, by investing in research and development to create innovative products. Thus, among the main impacts and lessons learned, the following may be highlighted:

- i. Demonstrating how research and development can be led by institutions in developing countries.
- ii. Developing phytomedicine protocols.
- iii. Generating new opportunities for training and employment through the introduction of non-traditional products.
- iv. Generating a sustainable use of biodiversity.
- v. Benefiting the whole chain of production, from the technicians to the farmers who provide materials.
- vi. Using the existing knowledge and technology in the country.
- vii. Using the benefits derived from payments received from the marketing of products to promote similar initiatives.

- viii. Offering high quality phytodrugs locally produced by *Laboratorios Lisan*.
- ix. Receiving royalties obtained from the sale of commercial products due to the signed agreement and which are shared equally (50-50) between INBio and the Ministry of Environment and Energy (MINAE) to promote the conservation of biodiversity.
- x. Avoiding excessive extractivism, with the materials being purchased from legal suppliers who cultivate their resources sustainably and complying with good agricultural practices (GAP).
- xi. Sharing results and knowledge to be transferred from INBio to *Laboratorios Lisan*.
- xii. Enabling the possible acquisition of patents for certain procedures and therapeutic applications.
- xiii. Placing six commercial products on the market.

Source: Rosales 2005.

INBio has files regarding executed bioprospecting agreements or similar agreements, recorded in databases individually developed for each project where they have logged everything related to: samples collected, collection sites, collectors and relevant associated information. An example of INBio's activity during the period 1991-2013, can be seen in 42 important contracts due to their high scientific level and application area (Table 4).

Table 4: Relevant Bioprospecting Agreements of INBio for collaborative research with industry and academia during the period 1991-2013.

Academic or industrial partner	Main purpose	Area of application	Period
Universidad de Cornell	Institutional Capacity Development	Chemical prospection	1990-1992
Merck & Co.	Plants, insects and microorganisms	Human and animal health	1991-1999
British Technology Group ECOS	<i>Lonchocarpus felipei</i> *	Agriculture and pest control	1992-2005
Cornell University, Bristol Myers and "National Institutes of Health"(NIH), "International Cooperative Biodiversity Group"	Insects	Human health	1993-1999
Givaudan Roure	Plants	Fragrances and essences	1995-1998
University of Massachusetts	Plants and insects	Agriculture	1995-1998
<i>Diversa</i> (now called VERENIUM)	Culturable bacteria DNA	Industrial applications	1995 – to present
INDENA SPA	Plants*	Human health	1996-2005
Phytera Inc.	Plants	Human health	1998-2000
University of Strathclyde	Plants	Human health	1997-2000

Academic or industrial partner	Main purpose	Area of application	Period
Eli Lilly	Plants	Human health and agriculture	1999-2000
Akkadix Corporation	Bacteria	Agriculture	1999-2001
<i>Follajes Ticos</i>	Palmas	Ornamental improvement	2000-2004
<i>La Gavilana S.A.</i>	Microorganisms	Agriculture	2000 – to present
<i>Laboratorios Lisan S.A.</i>	Plants	Human health and phytomedicines	2000-2004
<i>Bouganvillea S.A.</i>	<i>Quassia amara</i>	Agriculture	2000-2004
<i>Agrobiot S.A.</i>	Plants*	Ornamental improvement	2000-2004
University of Guelph	Plants*	Agriculture and conservation	2000-2003
“Chagas Space Program”	Plants, fungi* and marine organisms	Human health	2001- to present
SACRO	Orchids	Conservation	2002-2008
Merck Sharp & Dohme	Education and training	IPR Management	2002-2006
<i>Industrias El Caraíto S.A.</i>	Nutraceuticals	Human health	2001-2004
Harvard Medical School, International Cooperative Biodiversity Group R21	Endophytes	Human health	2003-2005
University of Panama and the OAS (Organization of American States)	Plants	Human health	2003-2004
Harvard Medical School and the National Cooperative Drugs Discovery Group (NCDDG)	Endophytes	Human health	2005-2008
Ehime Women College	Plants	Human health	2005-2008
<i>Laboratorios Vaco S.A.</i>	Microorganisms	Industrial applications	2005-2011
Harvard Medical School and the International Cooperative Biodiversity Group	Endophytes, lichens and marine organisms	Human health	2005-2009
Pfizer Institute	Microorganisms	Human health	2005-2006
UNDP, BIOTRADE, UNCTAD, CAF	Implementation of National Plan of Biotrade	Biotrade	2005-2006

Academic or industrial partner	Main purpose	Area of application	Period
National Council for Technological and Scientific Research (CONICIT)	Spiders (DNA)	Molecular taxonomy	2004-2005
CONICIT	Plants	Human health	2005-2006
Korean Research Institute of Bioscience and Biotechnology (KRIBB)	Plants	Human health	2008- to present
Harvard Medical School and the Medicine for Malaria Venture (MMV)	Endophytes	Human health	2007 - to present
CONICIT	Microorganisms	Industrial applications	2008
CONICIT	Establecimiento de ensayos respecto al <i>Aedes aegypti</i>	Human health	2007-2010
Superior Council for Scientific Research of Spain and the CRUSA Foundation	Microorganisms	Enzymes and industrial applications	2008
Superior Council for Scientific Research of Spain and the CRUSA Foundation	Microorganisms	Human health	2008
IDB-Chilean Fund and the Adolfo Ibáñez-Octantis University	Institutional Capacity Development	Management of enterprises	2008
University of Michigan and Harvard University (ICBG II- 2009-2013)	Fungi and microorganisms	Human health and bioenergy	2009 - to present
<i>Florex</i> of Costa Rica	Microorganisms and plants	Cleaning products	2010 - to present
<i>Pharma Mar</i>	Marine organisms	Human health	2012 - to present

Source: Cabrera Medaglia 2013.

* Organisms that produce DMDP (2R,5R-Dihidroimetil-3R,4RDihidroxipirrolidina).

When a review of literature and specific studies was conducted in Costa Rica (Ballestero, Reyes and Sanchez 2011; CINPE and INBio 2006; SINAC 2009; Ministry of Agriculture and Livestock et al 2008; Promoter of Foreign Trade of Costa Rica, 2011) and conversations and personal communication with some specialists was established (Jiménez, pers. com. 2013; Ramírez, pers. com. 2013; Quiroz, pers. com. 2013), national opportunities for innovation development and commercialization of products were identified in areas such as: enzymes for industrial processes; microorganisms for the biotechnology industry and crop protection, even in extreme environments; marine organisms for pharmaceutical research aimed at phytomedicines and natural supplements; some genetic enhancement of some crops through conventional means, and modern biotechnology.

3.2 Case Study in Cuba

In Cuba there is a major national capacity to conduct research on natural products, generating marketing results at a national and international level to develop new innovations based on genetic resources. One of the most prestigious institutions is the Drug Research and Development Center (CIDEM), created for research on medicines, nutritional supplements and cosmetics. This is why, it uses scientific development and advanced technologies to raise health standards in the country.

To this date, the CIDEM has an important set of products in the market, including phytomedicines, homeopathic drops, cosmetics and nutraceuticals, all of them derived from Cuban biodiversity as a result of its own research or, at times, in association with other national or international entities. The institution runs most or all of the activities in the country, so the products are available in their markets, as well as abroad. Thus, there are two examples of recognized bioproducts: VIMANG and VIDATOX (Table 2) (Cabrera Medaglia 2013).

Table 2. Two bioproducts generated with genetic resources from Cuba through endogenous activities of research and technological development, positioned in national and international markets.

Vimang

The research started from the basis of popular knowledge associated to the properties of the mango tree bark, which were identified by a Cuban professional who contacted national institutions, CIDEM and the Institute of Ecology and Systematics, and agreed to develop a research project in chemical bioprospecting.

With regards to the level of marketing, raw material from mango was used for the development of different drug formulations in the industry. Also, it should be noted that 48 scientific articles written by Cuban researchers and related bioprospecting were published.

The following are the main features of the bioproduct obtained from mango, both at a biological and phytopharmacological level, as well as in terms of patent identification:

- i. Name of the bioproduct: Vimang powder.
 - Biological resource properties: Scientific name: *Mangifera indica* L.
 - Family: *Anacardiaceae*.
 - Popular name: mango.
 - Resource used: tree bark.
 - Distribution: national.
 - Availability: cultivated plant.
 - Prospection type: chemical.
 - Finished product presentations: cream, liquid extract and tablets.
 - Pharmacological action: antioxidant.
 - Level of market penetration: commercialized.
 - Scope of use: generalized.
- ii. Patent (www.ocpi.cu)
 - Request No.: 1998-2003
 - Presentation date: 29/12/1998

Title: Pharmacological and nutritional compositions from the extract of
Mangifera indica L.

Number of certificate or publication: CU22846N1

Owner: Center of Pharmaceutical Chemistry, then ceded to LABIOFAM, the owner up
to date of the Invention Author Certificate valid until 29/12/2018

Vidatox

The research started from the basis of popular knowledge, specifically in the province of Guantánamo, associated to the properties of "red scorpion" venom in the treatment against cancer. The bioproduct is available in different homeopathic formulas. It is available in the Cuban market and international distribution is expected. The publication of some scientific articles written by Cuban researchers is underway.

The following are the main features of the bioproduct obtained from "red scorpion" venom, both at a biological and phytopharmacological level, as well as in terms of patent identification:

- i. Name of the bioproduct: Vidatox.
- ii. Biological resource properties:
 - Scientific name: *Rhopalurus junceus* Herbst, 1800
 - Family: Buthidae.
 - Popular name: "red scorpion".
 - Resource used: venom.
 - Distribution: national.
 - Availability: endemic species in low risk category.
 - Prospection type: chemical.
 - Finished product presentations: homeopathic drops.
 - Pharmacological action: analgesic, anti-inflammatory and antitumor.
 - Level of market penetration: commercialized.
 - Scope of use: generalized.
- iii. Patent
 - Request No.: 0186/2010
 - Owner: Drug Research and Development Center
 - Presentation date: 1994
 - Title: Peptides from the venom of the *Rhopalurus junceus* scorpion, pharmaceutical composition
 - Number of certificate or publication: CU 22413, invention author.
 - Request granted: June 21, 2012
 - Validity: 11/01/2014
 - Owner: Drug Research and Development Center
 - Protection abroad: Use of the Patent Cooperation Treaty System.

Stakeholders in the process of research and development

The research, development and commercialization were conducted in different institutions of Cuba, without the participation of foreign counterparts. However, in the case of Vimang, at one point a Belgian institution participated under a contract that outlined responsibilities, rights and other aspects, one of them being intellectual property.

The involvement of local communities or indigenous peoples did not exist during the process, but in the case of the venom of the "red scorpion" there was a popular use which, since the eighties, was believed to have an anti-cancer effect. Also, for the Vimang, research was developed from local knowledge regarding the properties of the bark of the *mango* tree. However, it is unknown if they belong to a particular group of people.

Benefits generated and shared to date

Bioproducts Vimang and Vidatox have positive results for conditions reported within traditional and/or popular use, and they are marketed nationally and internationally. However, sales data that reports the quantity sold, the uses in different sectors and the income perceived is still required.

The benefits generated by the two bioproducts are monetary since they represent new treatments for certain health conditions. In the absence of contractual agreements with third parties or among Cuban institutions responsible for research and development, the non-financial benefits are unknown. In addition, the publications that provide information on natural products could also be mentioned as products.

In Cuba, the development of bioproducts can prove its scientific research capacity and position them in the market. Regarding socio-economic conditions, the main impact is to have two bioproducts available and using the economic resources they generate in actions aimed at the welfare of the population, such as health and education.

Lessons Learned

Among the lessons learned, we can highlight the following:

- i. The existence of scientific institutions with endogenous capacity to add value to genetic resources, transforming them into bioproducts which are positioned in the market is an example of why it is essential to develop national capacities to improve health conditions. Furthermore, the registration of two patent applications was achieved indicating the possibility of generating innovations stemming from the biodiversity of the country and which are protected by systems of intellectual property rights.
- ii. The Popular knowledge was used in the case of the two bioproducts and had to be considered in the distribution of benefits, but there were no legal provisions in this field. Additionally, the benefits channeled __ towards biodiversity conservation and local populations is not determined, except in terms of the availability of new medical treatments and products in accordance with the socio-political model of Cuba.
- iii. Both studies use chemical prospecting of genetic resources to develop bioproducts, reaffirming the importance of considering the issue of access within the context of benefit sharing frameworks as provided by the Nagoya Protocol (Art. 2).

3.3 Andean countries: Colombia, Ecuador and Peru

In the Andean region, biotrade is implemented according to the proposal of the UNCTAD and its initiatives focus on the trade of species, extracts and commodity derivatives. Additionally, ecosystems are included to some extent in tourism initiatives, but projects on commercial use of genetic resources are still required. Some examples of products for basic or first phase biotrade are: essential oils and

oilseeds; gums, latex resins; colorants and dyes; spices and herbs; medicinal plants and byproducts; and tropical flowers and foliage (General Secretariat of the Andean Community, CAF and UNCTAD 2005).

The Andean Biotrade Program (PAB) originated at the World Summit on Sustainable Development in 2002 as a proposal from the UNCTAD, the General Secretariat of the Andean Community of Nations (SGCAN) and the Andean Development Corporation (CAF). The first phase of biotrade, is characterized by meeting consumer demand for natural products and compounds. The start of the PAB is in the five countries that were members of the Andean Community and is conducting the following projects:

- i. A private initiative in Colombia for butterfly rearing in the town of *El Arenillo* (Municipality of Ayacucho, in the Cauca Valley), promoting sustainable use and marketing in both national and international markets.
- ii. A community initiative led by women in Ecuador in the province of Chimborazo for the marketing of medicinal and aromatic plants, though there are others driven by civil society and indigenous organizations (UNCTAD 2012; Guamán 2011; Arévalo 2011).
- iii. A program of a non-governmental organization (NGO) in Peru focused on the sustainable development of rural communities in the province of *La Union* (Arequipa) by promoting community based tourism.

In the Amazon region there are initiatives similar to those in the Andean region because after the Declaration of Manaus in the VIII Meeting of Ministers of Foreign Affairs of Amazonian countries and the São Paulo Consensus, within the context of the eleventh period of sessions of the UNCTAD (2004), it was agreed –in conjunction with the Amazon Cooperation Treaty Organization (ACTO) – to establish a Regional Program for Biotrade in the Amazon. Thus, the "Implementation of the Biotrade Initiative of UNCTAD in the Amazon Region" program started, running from January 2000 to July 2004 (UNCTAD 2004). Similarly, biotrade initiatives are oriented towards processing and marketing of goods and services derived from native biodiversity in a sustainable environmental, social and economic way, oriented towards identifying, documenting and bringing biodiversity resources or products to market. Additionally, other regional programs are in place (<http://unctad.org/en/Pages/DITC/Trade-and-Environment/BioTrade/BT-Regional-Programmes.aspx>).

At a country level, initiatives follow similar criteria as the study called "Diagnostics for the formulation of the regional program of biotrade of the Amazon for Bolivia, Brazil, Colombia, Ecuador, Guyana, Peru, Surinam and Venezuela," sponsored by UNCTAD, GTZ, ACTO and the Alexander von Humboldt Institute (IAVH) (UNCTAD et al 2006, SGCAN, CAF and UNCTAD 2005). The analysis carried out in 2006 presented four product groups derived from local knowledge and management, seeking to position both promising species, as well as the set of goods and services from biodiversity in green markets to be commercialized.

In the case of the Colombian Amazon, trade areas of biodiversity are represented in four groups: exotic fruits and medicinal plants; non-timber forest products, wildlife and ornamental fish; ecotourism and handicrafts manufactured with fibers and seeds (<http://www.caf.com/es/areas-de-accion/medio-ambiente/biocomercio/proyecto-gef-UNEP-caf>). The analysis related to value chains

and biotrade for this region evaluated 49 business initiatives, focusing its activities on: Amazonian fruit (23%), handcrafts with wood, fibers and seeds (40%), and flowers and foliage (14%) (Arcos et al., 2009).

A Report on the Biotrade Initiative points out some achievements in the growing market for their products, which resulted in total domestic and international sales of \$223.4 million USD in 2007 and \$238.7 million USD in the 2008 for Andean countries. Data highlighted Peru as the country with the largest value in exports, .U.S. \$ 111.9 million USD in 2007 and \$114.6 million USD in 2008 (UNCTAD 2012). Regional initiatives expand and influence the approach for trade in biodiversity at the country level. For instance, in 2002 the Ministry of Environment and Sustainable Development (MADS) of Colombia formulated the National Strategic Plan for Green Markets. Its objectives were: identifying and promoting methods of production and marketing of healthy environmental goods; increasing the supply of environmental services in the competitive market; consolidating a national and international specific demand, and structuring the framework required for their development (Melgarejo, 2003). Nowadays, the Ministry of Environment and Sustainable Development (MADS) has a specialized section called the Office of Green and Sustainable Business.

The IAVH boosted the Sustainable Biotrade program as part of the program of Use and Valuation of Biodiversity in 2005, and with the support of the World's Bank program Global Environmental Fund (GEF)-Andes the Biotrade Fund was created in response to: the Millennium Development Goals, the 2019 Agenda for Colombia, the National Development Plan and the National Strategic Plan for Green Markets. In 2006, the Biotrade Fund is established as an NGO (<http://www.Fondobiocomercio.com> /), which leads the creation and support of initiatives that use biodiversity with the involvement of local communities and subject to international funding.

Initiatives that participate in the Biotrade Fund NGO include non-timber forest products, ecotourism and farming systems that involve 59 companies whose practices respect the approach established by UNCTAD since 1996 (UNCTAD 2012). In 2013, the entity sponsored 103 projects regarding value chains for: food products (57%); pharmaceuticals (2%); cosmetics (5%); ornamental plants (4%), and ecotourism (31%). Among the initiatives we find *Ecoflora S.A.*, a firm that concentrates on the technological development of resources from biodiversity and whose parameters operate with the Union for Biotrade, focusing on creating products for the food and cosmetics industry with plants such as "*jagua*" (*Genipa americana*) and "*laurel de cera*" (*Myrica pubescens*) (Union for Ethical Biotrade, 2013).

At a later stage, an analysis of the market for natural ingredients is conducted in Colombia with an emphasis on the food, drugs and cosmetic industries (FDC), seeking to link biodiversity value chains with the marketing of products in the international market. In itself, the analysis takes biodiversity as a source of either animals, plants or other organisms with their products made from solid or liquid substances for ingestion or external use with therapeutic, hygienic or aesthetic purposes. Also, agro-industrial transformation processes (cultivation, management, harvesting, transport and storage) and technological transformation processes (extraction, stabilization and mixing) have been taken into account. During a preliminary inventory of native source products, 74 were identified and classified (Legiscomex, 2006), presenting a portfolio of nine categories of natural ingredients (GCUJTL 2009):

- i. Dyes the tints
- ii. Active ingredients for therapeutic purposes
- iii. Seasonings, spices and fruits with added value for sweeteners, agglutinants and flavorings
- iv. Aromatizers
- v. Essential Oils
- vi. Fats, waxes and butters
- vii. Saps, gums, resins and oleoresins
- viii. Juices, pulps, extracts, and concentrates
- ix. Flours and starches

One of the features of the identified natural products is that several of them have more than one use, belonging to more than one of the nine categories of ingredients similarly, each category can have a variety of sources corresponding to various biological organisms and productive contexts. The GCUJTL (2009) conducted a focalized study for FDC sectors which recognizes the context of increasing demand, requesting bioproducts without: additives dyes, natural preservatives or compounds obtained by chemical synthesis. Also, the preservation of the environment, the respect for the rights of workers and the recognition of the contribution of indigenous and local communities is demanded. In addition, studies of commercial and technological surveillance have an impact on three categories of natural ingredients (GCUJTL 2009):

- i. Saps, gums, resins and oleoresins, particularly "*aji*" (*Capsicum spp.*) and "*dividivi*" (*Tara spinosa*).
- ii. Juices, pulps, extracts, inputs, and concentrates, especially "*arazá*" (*Syzygium jambos*) and "*açaí*" (*Euterpe oleracea*).
- iii. Colorants and dyes, specifically "*achiote*" (*Bixa orellana*) and "*Jagua*" (*Genipa americana*).

Framed within FDC sectors, the results of the commercial monitoring study show a growing demand of consumers who opt for products that are optimal for health and nutrition, as they have minimal or no components of chemical synthesis. It is worth clarifying that commercial surveillance is understood as the systematic and organized effort of observation, collection, analysis and dissemination of accurate information in order to identify market trends in processes and products, from the customer /supplier environment that may affect the future of an organization (Fúquene and Torres 2007, quoted in GCUJTL 2009: 34). In this report, it is emphasized that "the pharmaceutical sector for gums, resins, gum-resins and oleoresins shows an interesting dynamic with an increase in demand between 2003 and 2007 of 14% and of only 7% in supply, demonstrating an opportunity for unmet demand" (GCUJTL 2009: 55). In the cosmetic sector, there is an increase in the demand for fats and oils which surpasses the supply, unlike the juices and natural extracts sector which presents the opposite scenario given the various foreign producers available. In the food sector, there has been a proportional growth in the North American and European markets in both the food and natural ingredients segments, even showing a growing trend in demand and supply. In summary, researchers highlight the need to conduct further analysis beyond the limited one allowed by the four-digit importation tax records, while still emphasizing that the data shows a growing demand which is unmet by the supply, which in turn translates into opportunities for natural ingredients.

The GCUJTL (2009) contributes with information regarding the FDC sector with their study about technological monitoring, which is understood as the organization for the planning, search, analysis and dissemination of the information with the objective of monitoring scientific and technological development (Castellanos et al. 2006, quoted in GCUJTL 2009: 57), and is applied to three categories of natural ingredients at a national level. Given the fact that biotrade is a worldwide strategy, the results of this contribution would be limited. It must also be taken into account that Colombia shares biodiversity with other Amazonian and Andean countries, and that the principal markets are outside the Andean region. Additionally, this document includes only eight patents in history and they are related to three products ("*aji*", "*dividivi*" and "*achiote*") of the six priority products (GCUJTL 2009), and its basis is a revision of the state of the art in scientific research at a Latin-American level.

Another contribution of the aforementioned analysis, is related to technological innovation for natural ingredients worldwide, placing emphasis on priority products and citing the patent study about agro-biodiversity of Peru (Pastor 2008, quoted in GCUJTL 2009) which documents a total of 946 registries. In this context, it is worth pointing out that the five countries with the largest number of patents which amount to 72% of the international total are: Japan (303); the United States of America (182); the Republic of Korea (108); China (48), and the United Kingdom (36). Other countries that hold a high number of patent registrations are: the Netherlands, Germany, Switzerland and India.

When the search for patents is restricted to the species prioritized in the commercial and technological monitoring study, the results show a total of 225 registries for the period of 1957-2009. In the analysis of market opportunities it is relevant for a native product such as "*aji*" to have developments out of the area of transgenic varieties resistant to stress, fungi and bacteria, as well as to have agronomical properties that add nutritional value and modify the times of post-harvest (GCUJTL 2009). Thus, with the development of transgenic varieties under patent law, the local production and the participation in markets could be limited to the holders of patents, with Brazil being the only country standing out in patent registration among the countries of the region, due to its technological innovations linked to "*açaí*", "*dividivi*" and "*achiote*".

Within this patenting scenario, European countries like the Netherlands, United Kingdom, Germany and Switzerland have patent records; as well as the Republic of Korea and India. Also, the dominance of the United States and Japan is clear, while Brazil and India appear scarcely in terms of the ownership of technological innovations on native cultures of the diversity of the region. These are indicators of the technological gap between countries contributing the biodiversity and countries developing and controlling technological innovations. It is evident that the countries of origin of genetic resources such as the plant varieties selected in the study, need to position institutions involved in technological development.

The GCUJTL (2009) highlights the potential of the country with 145 varieties registered without research development which also reports that one quarter (34/145) of these correspond to native biodiversity. It is also mentioned that there are 111 research groups in universities, research centers and companies that will allow the country to conduct studies on agro-industrial issues. In addition, the analysis shows that research reflected in publications makes emphasis on product search and postharvest studies, but indicates lack of research to develop products with high added value.

Lozada and Gomez (2005, quoted in UNCTAD, 2012) studied the dependence on domestic markets of biotrade initiatives and they mention that out of the 100 initiatives analyzed, their marketing

percentage is: 63% in the local market, 50% in the regional market and 29% in the domestic market. They also add that only 16 have access to the global market. In addition, researchers agree with the report of the GCUJTL (2009), saying that the limitations of trade and leadership in the international market are associated with the limited addition of value to the products.

In Colombia the work of the Amazonian Institute of Scientific Research _ (SINCHI) that operates in the Amazon region is important because being a non-profit corporation linked to MADS, it works in functions such as "Getting, storing, analyzing, studying, processing, providing and disseminating basic information on the biological, social and ecological reality of the Amazon region in order to manage and use the renewable natural resources and environment of the region" (<http://www.sinchi.org.co>). In recent years, the SINCHI supported the building and strengthening of value chains with plants from the Amazonian biodiversity with promising results is a fruit known as "*camu camu*" (*Myrciaria dubia*) because its pulp is sold in Bogota for juice production, with its commercialization reaching four tons during its first operation in 2013. However, despite the good prospects of trade of the pulp, it is essential to give it a use which allows the fruit to increase its selling price in order to boost profits in the chain, and to reduce the percentage of money spent on transportation. For this reason, the SINCHI provided support to the chain by transferring the microencapsulation technology for "*camu camu*" in order to market it as vitamin C, since it is reported that its concentration of the vitamin is the highest among Amazonian fruits (Hernández *et al.* 2010).

In Peru, the efforts made by the Ministry of Environment (MINAM) and the Ministry of Foreign Trade (MINCER) to boost biotrade are notorious. However, they are not actions specifically aimed at the market of genetic resources. The National Program for Promotion of Biotrade (PNPB) was established in 2004, directing efforts to positioning final natural products in priority markets (Ingar Elliott, pers. com. 2013). The PNPB was introduced to coordinate multi-sectoral actions based on the objectives of the National Strategy on Biological Diversity. Similarly, the Integrated Foreign Trade Information System (SIICEX) supports the initiative to conduct market research and specific trade profiles for "*tara*", "*sacha inchi*", "*quinua*", "*kiwicha*" and "*camu camu*" for European and North American demand. (<http://www.siicex.gob.pe>).

In 2012 Peru, forms the Group of Research and Innovation in Biotrade, developing an agenda for strengthening competitive conditions of _ value chains for biodiversity products, which is shared among key institutions such as the National Council for Science Technology and Technological Innovation _ (CONCYTEC); the Ministry of Environment (MINAM); Peruvian Institute of Natural Products, and the *Peru Biodiverso* Project (PBD) (GII B 2012). The initiative promotes the recognition of research, development and innovation efforts (R + D + i) as well as the coordination that links the public, private and academic sectors to Biotrade. Another institution providing support in this area is the Institute for Peruvian Amazon Research Institute (IIAP) which belongs to the Technical Secretariat of the National Commission for the Promotion Biotrade. The IIAP promoted production chains in agriculture and aquaculture, developing research in order to document native fruit and medicinal plants, as well as studying biodiversity to enhance its use in conjunction with a map of stakeholders including: producers, environmental authorities, universities, regional governments, NGOs and entrepreneurs (IIAP 2009).

For IAP as a regional institution, the presence of indigenous and local communities in areas of high biodiversity as the Amazon involves an additional challenge for the conservation and appreciation of traditional knowledge, which requires an intercultural approach in the design of an innovation system (IAP 2009). The understanding of the complexity of the topic and the participation of multiple stakeholders for the IAP was reflected in the establishment of a Regional System for the Peruvian Amazon (SIRIAP) that interacts with the subsystems of Science and Technology, Environmental Management and Productivity (IAP 2009).

Approaches to the development of technology-intensive products require a comprehensive view such as the one proposed by the IAP, when it states "if a road can be built from traditional knowledge towards modern technology, you get to lay the foundations for moving from _ scientific knowledge networks to production chains, where analysis starts with a specific focus on demand and not necessarily by the review of the existing or potential production supply "(IAP 2008: 20). Therefore, efforts are focused on sustainability initiatives and socioeconomic inclusion of SMEs.

In Ecuador, the National Plan for Good Living includes Bioknowledge as an area that links social and biological sciences, placing biodiversity as a source of knowledge from basic research to sustainable development. Bioknowledge is presented as a wide range which includes everything from the industry based on ecosystem goods and services to conservation, research and sustainable use of biodiversity, this approach being a guide for the construction of a National Agenda for a Bioknowledge Strategy (Hail and Rios 2011). Thus, in the case of this country, rights on biodiversity will require a particular conceptual interpretation because the Constitution of the Republic of Ecuador adopted in 2008 provides for the protection of and respect for nature based on "*Sumak Kawsay*", a Kichwa expression which translates to "Good Living" in Spanish (Albán 2011).

The National Autonomous Institute for Agricultural Research (INIAP) of Ecuador conducts research and collection of traditional crops for human consumption, namely: "*achiote*", tree tomato, amaranth, papaya, cocoa, passiflora, 200 types of "*naranjilla*" and "*aji*", 500 types of native potato, "*melloco*", "*oca*", "*mashua*" and 29 varieties of corn (Tapia 2011). The role of INIAP is strategic, because just as the National University of Loja, the institutions are running *ex situ* conservation through their germplasm banks (Tapia 2011). In this context, Ecuador promotes scientific and technological progress, recognizing the concept of *Sumak Kawsay* and projecting innovation, in order to exploit nature with its diversity of genes, species and ecosystems.

The absence of specific studies on the current scope or weight of biotrade on national economies, leads to looking at the market for genetic resources through indirect sources. However, this approach is difficult in sectors that group information because the product categories for biotrade prevent the collection of data about trade flows related to genetic resources (UNCTAD 2012). In general, there is no specific tariff code for new biodiversity products because although exported, they are not included as "commodities" (Hughes 2007). And so, we can differentiate figures regarding export volume and value of broad categories such as botanical products or ingredients, but not as genetic resources (Table 5).

Table 5. Volume and value of botanical ingredients exported by four countries in 2008.

Country	2008	2008
	Export Volume (kg) Botanical Ingredients	Export Value (US\$) Botanical Ingredients
Colombia	11'093.239	42'908.705
Ecuador	8'071.581	31'328.275
Guyana	447.471	539.830
Peru	107'878.633	243'929.720

Source: Brinckmann 2009, quoted in UNCTAD 2012.

The authors of this paper determine the amount of money traded for exports during the period 2008-2012, only when they analyze certain data with the Trade Map program (<http://www.trademap.org>) such as considering five types of products that correspond to biological resources, genetic resources or derivatives, such as: fibers (Tariff code 14); essential oils (Tariff code 3301); natural vegetable alkaloids (Tariff code 2938); vegetable saps and extracts (Tariff code 1302), and seeds (Tariff code 12). The annual performance of exports for each country when the five listed products are added, has a tendency to grow. However, it has turned out to be dissimilar because Peru and Costa Rica exceed the participation of Colombia and Ecuador (Table 6).

Table 6. Export trends for five natural products (fibers, essential oils, natural vegetable alkaloids, vegetable saps and extracts, and seeds) added in eight Latin American and Caribbean countries during the period 2008-2012.

Country	Value exported in thousands of dollars (USD)				
	2008	2009	2010	2011	2012
Colombia	18.608	14.059	21.618	25.409	29.330
Costa Rica	43.000	27.040	36.999	43.348	52.960
Cuba	875	1.164	715	1.586	1.150
Ecuador	3.746	3.041	6.492	9.769	11.572
Guyana	731	1.189	615	601	101
Panama	6.578	3.185	2.014	3.468	2.645
Peru	99.189	86.256	116.993	135.912	173.996
Dominican Republic	12.186	10.513	13.107	17.360	16.919

Elaboration: Dalí Alejandra Rojas Díaz 2013.

When considering the joint participation of the eight countries in the worldwide market for the five products mentioned above, the results demonstrate that their role is still marginal. In the case of Peru, their share is above 1% in the fibers segment when exports for the period 2008-2012 are added. Thus, the eight countries need to position their products in international trade. If we take, for instance, vegetable alkaloids, their participation reaches only 0.02% in contrast to Germany which has 57%. In addition, other examples worth mentioning are those of Indian vegetable saps and extracts with 32% and essential oils that amount to 14.4%, as well as the United States of America in the seed sector where it has 30.1% participation.

4. Bioprospecting and genetic resources market

In this approach to establish market opportunities for genetic resources in the eight countries analyzed, it would have been necessary to have an updated baseline. Studies of technological monitoring and competitive intelligence are exceptional in countries of the Andean region and the Caribbean. Even the analysis of the trade of specific plant species in the markets of some countries is based on existing information, as is the case of "*camu camu*" and "*sacha inchi*" of the biotrade program of Peru (Hughes 2007).

In Colombia, the analysis of the pharmaceutical, food and cosmetic industries has been grouped together (GCUJTL 2009) and there is a study of technological monitoring on metagenomics carried out by the Colombian Center for Genomics and Bioinformatics of Extreme Environment (GEBIX) (Caraballo and Rojas 2010). It is focused on enzymes for industrial application for the period 2005-2010. However, experiences of partnerships between academia and industry have been found. Thus, it should be mentioned that abroad, interdisciplinary teams, as well as alliances and partnerships between academia and enterprises where formed for creating and sequencing of metagenomic libraries. In relation to scientific publications in this field, it is U.S., German, Korea and Chinese researchers who have the highest register. In contrast, Latin America has three publications from Brazil and a joint one from Mexico and Argentina. As regards patent applications and the number of granted patents, when researching the databases of the WIPO, USPTO and Esp@cenet, the countries that stand out due to their high turnout are: the USA, the Netherlands, France and Germany, in descending order.

The analysis of bioprospecting and markets in the Andean region presented is based on existing documents, workshops, seminars and case studies. One of them is the one brought forth by the CAF and the Economic Commission for Latin America and the Caribbean (ECLAC) on "Biotechnology for the sustainable use of biodiversity: local capacities and potential markets" (Quezada et al 2005.). In this report, market opportunities were analyzed by performing a synthesis of three studies: the first, on potential economic and commercial exploitation of biodiversity in the Andean countries; the second, about trends in the development of biotechnology capabilities in the region; and the third, regarding recommendations and guidelines on strategic policy. The results present the discussion and evaluation of national studies and seminars with the participation of relevant stakeholders in the region.

In Colombia, interest in industrial and commercial exploitation of biodiversity and associated knowledge is reflected in the government plans and programs of the first decade of this century. Biotechnology is assumed as one of the pillars of entrepreneurial and productive socio-economic development by establishing strategies for: the "National Policy on Competitiveness and Productivity"

(CONPES 2008), the "Policy for the Promotion of Research and Innovation: Colombia builds and plants its future" (COLCIENCIAS 2008) and the "National Policy on Science, Technology and Innovation" (CONPES 2009). These strategies focus on the use of genetic resources in applications for agriculture and other industries. The diagnosis carried out by COLCIENCIAS validates the advances in biotechnology and compiles them in the report entitled "Biotechnology, the Engine of Development for Colombia 2015" (COLCIENCIAS 2005), presenting it as a one of the "locomotive" for economic growth, as it is proposed in the "Basis for the National Development Plan: Toward Democratic Prosperity, Vision 2010-2014" (National Planning Department 2011).

The aforementioned policies have excluded indigenous peoples, afro descendants and local communities from participation, even where legislative mandates are in force as is the case of the National Council of Economic and Social Policy (CONPES) 3697. However, the reformation of the National System for Science and Technology and of the Colombian Institute for the Development of Sciences and Technology (COLCIENCIAS), by virtue of Law 1286 of 2009 through which COLCIENCIAS is transformed into the Administrative Department includes the following objective: "Promoting and strengthening intercultural research, in coordination with indigenous peoples, their authorities and elders, with the goal of protecting cultural diversity, biodiversity, traditional knowledge and genetic resources" (Art. 6, Paragraph 11, Law 1286 of 2009) (Nemogá-Soto 2013). The policy established by the CONPES 3697 also includes the following goal: "[...] creating all the economic, technical, institutional and legal conditions that make it possible to attract public and private resources for the development of commercial companies and products based on the sustainable use of biodiversity, specifically of biological and genetic resources and their byproducts. These resources are the basis of new products for diverse industries such as the cosmetic, pharmaceutical and agri-food industries, and that of natural ingredients, among others." (CONPES 2011: 2).

In this biotrade scenario, it is essential to have a clear articulation within the policies that promote it, as well as technological development applied to biodiversity. For this reason, the development goals of scientific research on native genetic diversity and the possible outcomes for industrial or commercial application must be interrelated in the regime of access to genetic resources. In practice, the implementation and operation of access regimes has been traumatic for national research systems (Nemogá-Soto 2010). Systems of access to genetic resources nowadays need to safeguard the rights of the countries of origin, as well as the participation of indigenous and local communities in their knowledge. In addition, in areas with a high technological component, such as metagenomics, developments should be led by joint ventures between research groups and SMEs with clear benefits and a system of access to genetic resources that facilitates both scientific research, and initiatives to make industrial and commercial applications.

The benefit sharing component in projects with a commercial application is presented as an urgent challenge that countries must operate. These systems are generally unknown by researchers; however, compliance is essential for the development of projects involving access to genetic resources and their derivatives or biochemicals (Quezada 2007). Therefore, if this problem remains unresolved, research and technological development based on biodiversity can be limited by ineffective legal regimes, or possibly even constitute biopiracy. The lack of clarity and inconsistency in public policy on access to genetic resources at regional and national levels limit the ability of bioprospecting companies (Quezada 2007). In this sense, following the description of Quezada and his colleagues (2005), the following are considered relevant areas in biotechnology with access to genetic: biopharmaceuticals, nutraceuticals, cosmetics and personal care; industrial enzymes; agricultural biotechnology and genetically modified seeds, bioinformatics genomics and microarrays; and bioconductors.

4.1 Biopharmaceuticals

The biopharmaceutical industry includes both drugs and vaccines, used for diagnosing diseases in humans and animals, with studies usually giving preference to the subarea of monoclonal antibodies. Furthermore, developments in genetic engineering, genomics, proteomics, metabolomics, nanotechnology and bioinformatics are identified, since these are technological lines which contribute to the discovery of biopharmaceuticals. Technological innovation in biopharmaceutical requires a high capital investment, because technology infrastructure, qualified personnel and monopoly protection via patents over products and innovations are indispensable factors. The costs associated with research, testing new products for science, technology predominance with patents, turn the pharmaceutical market into an area dominated by large pharmaceutical companies. The costs associated with research, testing and development of new products, as well as the prevalence of patented technologies, make the pharmaceutical market an arena dominated by large pharmaceutical companies. In this sense, Quezada (2007) identified few companies dedicated to commercial bioprospecting in Andean countries, since it requires a high capital investment and long-time research to create new products, particularly in the pharmaceutical sector.

In this area there is a technological platform for natural compounds that are seen as promising sources of drugs compared to those developed synthetically; but due to the technological demands, the level of technical skills and investment requirements, the Andean countries only participate when they can add information to the biological resource. The indispensable sources for great discoveries are both ethno botanical research to document traditional knowledge associated with medicinal plants, as well as the processes of screening and mass selection carried out in the region.

Biodiversity is seen as a source for biocomposites not yet described, but with a huge potential for industrial or commercial application. An example of this being the commercial initiatives of biotrade in the southern Amazon of Colombia when they sold 17 million dollars (USD) in natural ingredients for the pharmaceutical and cosmetic industries (Arcos et al., 2009). Also, caution should be exercised when identifying and isolating genes for bioactivity that can be transferred to genomes of laboratory organisms for mass production, as it could be identified as a bioprospecting activity.

4.2 Nutraceuticals

The CAF study identifies the nutraceuticals market as the most promising one for Andean countries. In this category we find natural ingredients used as food supplements, proteins, vitamins, minerals and specific nutrients. At the same time, it is possible to find functional foods and include energy drinks, fortified juices and diet food.

Functional effects are attributed to nutraceuticals in terms of nutrition and health, which is why this area includes natural ingredients in foods and beverages that have great market potential for getting products without high financial, technological or regulatory requirements. Also, since they are considered natural substances that are present in biodiversity, there is no patent rights barrier for materials.

One issue to consider in the area of nutraceuticals, is that a substantial part of the identification of compounds of interest lies in local and traditional knowledge associated with the use and consumption of plants and animals. It is therefore necessary to develop approaches on fair and equitable benefit sharing with those who hold knowledge.

4.3 Cosmetics and Personal Care

The field of cosmetic and personal care is also among the most promising for the region due to both the low technology requirements, as well as for having medium-skilled human talent. However, the option is the provision of botanical and natural products for SMEs, because the final cosmetic products industry is dominated by large companies. Small and medium-sized providers can take advantage of factors such as the scalability in production, the insertion in associative networks and the supply of differentiating elements that enable them to participate in the markets" (GCUJTL 2009: 24).

Growth in this sector is based on the expansion of new segments of the population, consumers of personal care products and buyers of products that prevent the signs of aging. Thus, it aims to sell natural alternatives such as cosmeceuticals are cosmetic products with healing properties. For example, the organic compounds derived from biological organisms such as plants and algae which are the raw material for the development of skin-protecting agents. At the same time, individual cases such as "*camu camu*" and "*sacha inchi*" must be considered because they can be classified as dietary supplements, functional foods and cosmeceuticals.

4.4 Industrial Enzymes

Enzymes are widely used in industries such as those of: food, cleaning products, treatment of textiles and leather and paper processing, and are commonly obtained from plants, animals and microorganisms. Currently, enzyme technology innovation focuses on the modification of their structures by enzyme engineering and the discovery of new ones that are more efficient due to having new activity or withstanding extreme environmental conditions.

When analyzing environmental considerations and consumer preferences, the market for natural enzymes has greater demand than for enzymes produced in a lab, but innovation has high investment, technology and qualified human talent requirements. Establishing and sustaining metagenomic libraries and the platform for their analysis requires a large long-term economic capital.

The stages of scaling and production of industrial enzymes require partnerships with industry players to participate in the world market, because innovation requires technology platforms and highly qualified human talent. Countries with low public and private investment in research have a poor scientific and technical training, a situation which limits their possibilities. Additionally, the industry is highly competitive and all technological developments should be protected by intellectual property, particularly patents and trade secrets. The market potential for the Andean region lies in bioprospecting activities oriented to the discovery of enzymes with characteristics of industrial interest.

4.5 Agricultural biotechnology and transgenic seeds

The expansion of GM crops is a fact in the Andean region, and genetic engineering and biotechnology offer solutions to certain diseases, stressful environmental conditions and some crop pests. It should also be noted that there is some resistance to the use of GM seeds and their byproducts due to being a sensitive issue. In addition, technological innovation is controlled by a few companies with strong agro-biotechnological IPR, such as patents over germplasm, processes and products.

The generation of transgenic crops to produce proteins, enzymes and biomaterials for human use are not yet an option for countries in the region. In contrast, the development of biopesticides and biofertilizers for local or regional crops is an initiative in which some countries have ventured. The opportunities for the countries of the Andean region lie in the bioprospecting of wild relatives of commercial crops, in genes responsible for agronomic traits or in the production of crop of interest. The presence of a high plant endemism, and the existence of cultural practices that incorporate nutrition and healthcare, the use of plants, and partially documented species, are factors seen by Quezada and his colleagues (2005) as potential for new opportunities market.

4.6 Bioinformatics and Genomics

Bioinformatics focuses on the generation, storage and analysis of genetic data, but it is difficult to appreciate how the countries of the Andean region can lead in this field as consumers of imported high-tech software and hardware. Specialized advances and innovations of tools for specialized information analysis require a high scientific and technological infrastructure and are protected by intellectual property rights, essentially to generate databases in new disciplines such as genomics and proteomics or areas with different levels of resolution which are defined based on poor or non-existent research in the countries of the region such as metabolomics (metabolic pathways) and glycomics (complex sugars).

One factor which does not favor the Andean region is the rapid technological rotation, such as that in the genetic sequencing field which is just beginning to implement technology platforms and incorporate human talent to create competitive innovations. In practice, advances in metagenomics and bioinformatics are materialized in the use of existing tools for data analysis and for the generation of genetic information that is of public domain, such as the case of biofuels (Caraballo and Rojas 2010).

Nowadays, another unfavorable risk for countries with biodiversity is the need for authors to upload DNA sequences to public databases, because it is a requirement for scientific publications. In itself, the situation becomes an opportunity for companies with advanced technology in data mining, because they can identify and recognize the keys to new biopharmaceuticals, develop studies or exploit the information available in the public domain for industrial or commercial applications.

4.7 Bioconductors and Microarrays

The bioconductors and microarrays are related to the creation of biomolecule sets, microarrays (DNA arrays in slides or chips) and electronic and robotic innovations. These fields require capital investment, scientific and specialized technological capabilities and an intensive use of intellectual property to control the exploitation of the innovations. In itself, this sector is useful for biomedical and genetics research, automated reading of large DNA samples and the diagnosis of diseases or genetic variations.

5. Final Considerations

This analysis highlights aspects that must be addressed if countries seek to exploit market opportunities for genetic resources and their byproducts. Thus, it is found that despite the economic potential assigned to genetic resources and traditional knowledge, the situation in some countries needs to advance and specific studies are needed in order to get detailed information about the existing opportunities and the necessary conditions to exploit them, channeling political policies, investments and legislation to promote bioprospecting initiatives.

The countries participating in this study require political measures in the field of genetic resources, as well as an updated baseline in with prospective studies, technology monitoring and market intelligence. One crucial issue is the limited information available, which has been included in different revised studies and reiterated in a statistical exercise with Trade Map for natural product exports. Existing data is rather poor to be considered as reliable when looking at volumes, income and trends for exports of products directly associated with biotrade. Furthermore, the information available is partial and sometimes corresponds to literature addressing broader issues such as medicinal plants and biotrade, among others. For this reason, the data found or quoted is approximate and should be seen as indicative of general trends.

Within this context, it is emphasized that in some cases, policymakers must overcome preconceptions in order to make policies, because these might increase mistakes regarding the expectations of economic use of biodiversity. Unlike extractive industries for natural resources which are driven by designs of open markets and foreign investment, bioprospecting requires a financial capital based on innovation and development of endogenous research capabilities that are generally not contemplated by the science and technology systems of countries in the Andean region.

In the Andean region scenario, when considering substantial differences between biodiversity and oil, "the true economic potential of biodiversity in the near future is similar to that of oil, because the wealth of information contained in genetic material is incalculable" (Campos, 2011: 62). While it is true that the value of biodiversity is in specific genetic information, its identification, sequencing, utilization and management imply technology platforms that countries need to build. The analogy between oil and biodiversity underscores its value as an economic asset, independent from its ethical and ecological values, generalizing a false expectation to project the idea of biodiversity as "green gold" and seeing it only as a potential source of huge economic gains.

Nowadays, potential can be seen in areas such as bioremediation, biomedicine and biofuels, among others; but the probability that the Andean region will participate in these markets comes down to its scientific and technological capabilities, qualified human resources and investment in research as well as to freedom to operate in a field which is highly dominated by large companies with intellectual property over materials, products and processes. In addition, entering the international market is subject to compliance with very demanding health and trade regulations.

Arcos et al. (2009) provide a broad concept of innovation encompassing the market introduction of a new good, as well as production methods not yet experienced, the opening of other commercial niches and the conquest of supply sources of raw materials or the implementation of novel production structures. As such, everything requires the use of native biodiversity resources to introduce innovative elements in the products, creating options for countries. However, the challenges of developing endogenous capacities for cutting-edge scientific and technological research in strategic areas cannot be ignored.

When defining strategies and innovation agendas for bioproducts, countries with high rates of biological and cultural diversity must adopt an interdisciplinary and comprehensive approach. The reason for the above, is related to the fact that many expectations focus on biological and genetic materials found in indigenous peoples' territories, but the plans and programs exclude their participation. This situation is illustrated in the emphasis that the biotechnology "locomotive" has in Colombia (CONPES 2011). In close relation, the Agenda for Research and Innovation for Biotrade in Peru includes companies and producers, academia, support institutions, the State and citizens as stakeholders, but it does not include indigenous peoples and local communities (GLIB 2012). But in politics and international law, the progress achieved and the implications of introducing traditional knowledge as an important factor in the conservation and use of biodiversity stand out. Malpica (2005, cited in Quezada 2007) indicates the need to involve all stakeholders, including indigenous communities that possess traditional knowledge, participate in bioprospecting operations, as proven by the experience of the private business venture *Kina Biotech S.L.* in Peru.

Nowadays, when agendas and strategies for the use of biological and genetic diversity in market opportunities are being developed, it is necessary to recognize the challenges arising from the intellectual property system. In some cases, patents and other intellectual property rights overlap as a network that may limit potential national developments projected towards the global market, especially in countries that have agreed to raise the minimum IP protection as a part of free trade agreements. One example can be observed in the market study on "*camu camu*" and "*sacha inchi*", in which international patents registered in Japan and the United States of America were found on properties of "*camu camu*" and substances found in "*sacha inchi*" and other plant species (Hughes 2007). The case of Peru illustrates the need to implement comprehensive strategies, which include actions against biopiracy, legal measures of protection for traditional knowledge and institutional efforts to take advantage of market opportunities.

The different analyzes agree in highlighting the growth of the international market and the opportunities it represents for countries possessing biodiversity. The study corroborated the marginal role of eight countries in the market of five selected natural products based on the Trade Map tool. Thus, the results show that we can emphasize the opportunity for growth, but it is necessary to look at trends in national markets for natural products as a major opportunity. Countries with a local biodiversity with

potential for use often have a large number of imported natural products in their markets. An example of this is Colombia, where imports of natural ingredients for the food sector grew by 23.1% between 2006 and 2007. This figure is due to the fact that "every day new multinational companies are created and bring raw materials from their head offices (ICEX 2005, quoted in GCUJTL 2009: 23).

Bioprospecting developments in Costa Rica and technological innovations of Cuba show two alternatives that strengthen endogenous research capabilities, since they corroborate how processes of research and development can be led by national institutions. In fact, bioprospecting companies outside the region have forged strategic alliances with academic institutions, research centers and international companies and institutions (Quezada 2007). This is what Costa Rica does, being the leader in the generation of bioprospecting agreements between industry and academia, on training of human talent, lab implementation and project execution.

The experiences of Cuba and Costa Rica show the development of new commercial products based on technological innovations regarding biodiversity and its sustainable use. In both countries, the strengthening of national institutional capacities added value to productive chains that serve health needs. Also, advances in these countries demonstrate the use of tools such as intellectual property patents, accentuating the ability to generate innovations with a technological and economic impact.

Data on the size of the genetic products market, areas and sub products, limitations but allow for reflections on the market opportunities in the region; for example, international trade has a significant potential economic value derived from the use of genetic resources, although such value is not always directly attributable to these except in the case of seeds and horticulture. Similarly, the amounts traded are higher in areas where investment in research and development is high and regulatory frameworks are strict, limiting the possible participation of countries with poor technology and little venture capital for the product market as well as limiting the consecution of greater benefits derived thereof.

The analysis of the above information presents significant challenges to improve processes and national innovation systems related to biodiversity, as well as in other areas of research where the cost is lower relative to the genetic resource. Apparently, certain natural products are more promising for short-term monetary rewards, such as personal care and cosmetic supplements, among others, because their markets relate more broadly to biotrade activities. In countries participating in the project, there are still few successful and well-documented experiences in developing products and innovations related directly to the use of genetic resources, with the specific cases of Cuba and Costa Rica standing out in this respect.

Data on market opportunities has a partial value because opportunities depend on both the cost of goods sold or traded, and the way they could be exploited from the perspective of the countries. A better use requires having processes, policies, institutions, and adequate sources of funding. This is true in areas such as: inventories of genetic resources, conservation strategies and management of information sources, development of endogenous capacities, institutional articulation on the field of innovation, strategic alliances with the private sector, and management of intellectual property rights. They also need to include other aspects such as: knowledge systems of indigenous and local communities, biotechnology, crop protection, bioinformatics, genomics, metagenomics and proteomics, among others

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Interrelationship between indigenous worldview and biodiversity:
How to protect traditional knowledge and genetic resources?



Handicrafts in the Colca Canyon, Peru. © Sarah Johnson.

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Interrelationship between indigenous worldview and biodiversity: How to protect traditional knowledge and genetic resources?

Introduction

The emergence of a recombinant biotechnology applied to DNA made feasible the development of the industrial application of genetic material giving an unexpected economic importance to indigenous and local knowledge related to biodiversity uses. This new vision turned biological diversity into a reserve of natural material, as well as indigenous and local knowledge related to plants and animals in a basis for developing commercial products creating different dynamics and initiatives of bio prospecting with scientific and lucrative purposes. Nowadays, it is known that some initiatives exerted a misappropriation of genetic resources and traditional knowledge; generating regulatory processes to ensure participation in the benefit sharing derived from their utilization (ABS).

In this ABS context regimes of access to genetic resources are established under Arts.1 and 15 of the CBD because they recognize the sovereignty of countries of origin but even if traditional knowledge is mentioned a comprehensive protection is still needed. Also regulation as Decision 391 of 1996 included traditional knowledge as an intangible component of genetic resources and conditioned the granting of intellectual property rights on their innovations and legal access (Supplementary provision 2^a). While this regulation helped in the recognition of the rights of indigenous, Afro American and local communities to decide on the access and use of their knowledge, practices and innovations (Decision 391, Art. 7), the development of a comprehensive protection regime remained subject to the establishment of a harmonization regulation (Temporary Provision 8^a). The truth is that two decades have passed without establishing such regime or materializing national measures to prevent irregular appropriation of genetic resources and local knowledge related, except for Peru where there is a record of collective knowledge.

Peru's records are inspired in biodiversity record systems driven by some NGO's for biodiversity in India such as the initiative "Honey Bee Network" (Gupta 2000) which developed a digital library and promotes a model to combat misappropriation of traditional knowledge related to biodiversity, especially in traditional medicine systems (WIPO 2011). Documenting local knowledge and resources is directed to prevent obtaining and undue exploitation of intellectual property rights and enforces regulation on access and benefit sharing.

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This research examines protection and conservation of traditional knowledge of indigenous peoples and local communities using a theoretical approach on bio cultural diversity to comprehensively understand the interrelationships between traditional knowledge and biodiversity, and understanding and integrating indigenous worldviews in the design of protection systems. It also identifies international instruments that enshrine the rights of indigenous peoples related to their cultural identity, their traditional knowledge and natural resources; subsequently it specifies the frame of intellectual property that sets its protection with advantages and limitations. Finally, it reviews and values the Peruvian efforts of its record system of collective knowledge examining the scope of this mechanism for the conservation and protection of traditional knowledge, innovations and practices related to the conservation of biodiversity and its sustainable use.

2. Protection of traditional knowledge

Consistently, several statements and expressions from indigenous peoples' leaders indicate that conservation and protection of traditional knowledge are closely linked to land rights, their resources and the right to self-determination (Kari-Oca Declaration and Indigenous Peoples Earth Charter 1992; Mataatua Declaration on Cultural and Intellectual Property Rights of Indigenous Peoples 1993; Indigenous Peoples' Seattle Declaration 1999). Thus, it is said that traditional knowledge is an integral part of indigenous and local lifestyles that are displayed in permanent and dynamic interaction with nature. The implication of such interactions is simple and straightforward without ensuring the lands, the rights over their resources and the exercise of self-determination, making conservation of traditional knowledge impossible in a meaningful way for the survival of the people.

The position of indigenous peoples is based on their lifestyle and daily practice, and the interrelationship between traditional knowledge and the ecosystem dynamics of the lands inhabited has been documented by studies conducted in the different ecosystems, going from the Arctic to the deserts in Africa and from the Andes to the Pacific Islands systems, and showing the adaptation of human groups to changing environmental conditions (Infield 2001; Lauer and Aswani 2009; Gombay 2010; Woodley 2010). Traditional knowledge itself has an intrinsic and necessary articulation with worldview, rituals and spirituality of each people as their particular contents correspond to the local, socio-environmental context and are present in: the stories of origin; relationships with deities; ceremonies, and practices that make the bio cultural diversity.

The approach from bio cultural diversity recognizes the "close ties of traditional knowledge and biodiversity, traditional lands, cultural values and customary regulations, all of which are vital to preserve traditional knowledge" (Swiderska 2006: 17). Bio cultural diversity can be understood as "the diversity of life in all its biological, cultural and linguistic expressions that are interrelated and probably co-evolved within a socio-ecological adaptive system" (Maffi 2010: 5)

In this context, traditional knowledge is an integral part of cultural diversity and arises from the challenges and problem solving that communities face in all areas of life; and therefore, to ensure their generation and conservation communities need to be able to develop and maintain from their own worldview their interaction with the land and its resources.

From an indigenous worldview separation between knowledge and living beings, natural environment and social life is impractical for nature and humanity are not cleaved. Indissolubility between knowledge and the various manifestations of life has been demonstrated in community conservation practices documented by Swiderska (2006) under the concept of "collective bio cultural heritage", comprising "knowledge, innovations and practices of indigenous and local communities that are kept collectively and are inextricably linked to traditional resources and lands, to the local economy, diversity of genes, varieties, species and ecosystems, cultural and spiritual values and customary regulation shaped within the socio-ecological context of communities" (Swiderska and Argumedo 2006: 11). Additionally, experiences in Africa, Asia, North and South America referred by Maffiy (2010), reiterate that interrelationships between biological and cultural diversity are the basis of conservation efforts and cultural affirmation in community initiatives of several indigenous peoples around the world.

Indigenous peoples represent between 4.000 and 5.000 of the 6.000 languages spoken in the world, forming the largest cultural diversity yet representing only about 5% of the world population. The rapid disappearance of native languages means that the encoded knowledge within them is becoming extinct with negative consequences for indigenous peoples, conservation of biodiversity and for humanity as a whole (Oviedo, González and Maffi 2004). This suggests that interrelationships between cultural and biological diversity are relevant for the design of protection strategies of traditional knowledge and involve considering indigenous peoples and local communities lifestyles. In this regard, the preservation of conditions that will ensure the generation of knowledge requires halting the loss of cultural diversity typical of mega diverse countries and it is equivalent to preserving adaptive solutions developed by humanity in different geographical contexts when considering social and environmental problems (Maffi and Woodley 2010). In the Americas indigenous peoples and those brought from Africa as slaves, survived the devastating practices of colonial empires. Subsequently, their very existence was hampered by assimilation and elimination policies driven by several governments who sought to forge homogeneous nations. Despite these processes, most of the indigenous peoples and Afro American and local communities kept their worldviews as the basis of interaction with nature; especially with plants and animals, and continued developing collective knowledge which allowed them to adapt and survive.

2. Recognition of the indigenous worldview

Concepts related to indigenous peoples themselves and to the communities whose knowledge is intended to be protected become relevant from a bio cultural diversity perspective. *Suma Qamaña* or Good Living is the expression of the aspiration of indigenous peoples to have fullness of life assuming responsibility and respect for all being of nature and recognizing human species as part of it. In Ecuador the term kichwa *Sumak Kawsay* is used to describe Good Living; however, the nodal elements of this view match the principles of other indigenous peoples in the south of the continent as described by Uzeda (2009), Huanacuni (2010) and Ascarrunz (2011). In the north, indigenous peoples of Canada use the expression *Mino bimaadiziwin from the Anishinaabe* (Ojibwe) people which could be translated as Living Well or Good Life (McGregor 2006). This concept in itself recognizes the intrinsic value of nature and every living being by the mere fact of their existence.

In this regard, it must be said that indigenous worldview, economic valuation and exchange of knowledge do not become the main focus or priority of their protection and conservation systems. Clarifying that Good Living is a conceptual statement against the commercial emphasis on natural resources that has driven the extractive processes of great environmental impact: "We will continue strengthening and defending our economies and rights over our lands and resources against extractive industries, predatory investments, appropriation of lands and territories, forced displacement and unsustainable development projects. These include large hydroelectric dams, plantations, large-scale infrastructure, tar sands extraction and other mega projects, as well as the theft and appropriation of our biodiversity and traditional knowledge" (Rio+20 Indigenous Peoples International Declaration on Self-Determination and Sustainable Development 2012). The concept of Good Living and cultural elements of the worldviews of indigenous peoples is starting to be recognized in the agenda for debates on traditional knowledge and the need of a comprehensive system validating the protection and conservation of collective knowledge (SPDA y SGCAN 2012).

Indigenous worldviews and lifestyles have priority for their collectiveness rather than for individual rights, this is why their dynamic and adaptation to changing situations rather than preventing access and controlling the availability of knowledge require the active exchange and intergenerational transfer of strategic information, skills and knowledge. The widespread of knowledge to solve health problems, feeding, housing, social cohesion, crop conservation as well as use, innovation and practices related to biodiversity are a collective adaptation whose appropriation and individual control would be a disadvantage for the survival of the human group in a changing environment. Collective knowledge of the Inuit people on "*caribou*" in the Arctic for example, ensures that the community can react properly to changes in the population of this species and their migratory cycles along the years, as documented by Berkes (2008). Similarly, knowledge and collective knowledge of Andean people to preserving crop diversity, cultural practices and related ceremonial rites sustain their permanence in an environment that is constantly changing (Ishizawa 2010). The collective nature of institutions, practices and rights of indigenous peoples is recognized in the international law.

2. Collective rights of indigenous peoples

Rights over traditional knowledge are recognized in various international instruments and provide a basis for the design of mechanisms that meet the needs and interests of indigenous peoples; although it does not define the ownership over traditional knowledge, CBD creates an obligation for countries to promote the use of traditional knowledge and to have the consent of indigenous and local communities for access. The scope of the “protection of traditional knowledge, innovations and practices” contained in article 8(j) goes beyond establishing standards of legal protection over knowledge, as stated by the CBD’s Executive Secretary (Executive Secretary, Secretariat of the Convention on Biological Diversity 2004).

CBD focuses protection on knowledge, innovations and practices related to biodiversity but extends its recognition to lifestyles of indigenous and local communities that interact and promote the conservation of biodiversity. Additionally, Art. 10(c) of the CBD states that signatory countries should promote the use of customary law which is relevant for the design of protection systems. Other instruments such as FAO’s International Treaty on Plant Genetic Resources for Food and Agriculture in Art. 9 (2, paragraph a) recognizes the responsibility of governments to take measures to protect and promote the rights of farmers and their traditional knowledge.

In the development of legislation and protection systems, signatory countries of the 169 Convention of the International Labor Organization (ILO) are committed to protect their values and social, cultural and spiritual practices under customary law and in consultation with indigenous peoples as stated in Arts.5.1, 8.2 and 13.1. The commitment to take measures to ensure “full realization of social, economic and cultural rights of these peoples with respect of their social and cultural identity, their customs and traditions and their institutions” is also provided in the Convention in Art. 2.2.b. The obligation to ensure the rights of these peoples “to the natural resources on their lands” (Art. 15.1, ILO 169) and the right to education programs covering “their knowledge and technologies, their value systems and all other social, economic and cultural aspirations” (Art. 27.1, ILO 169), conditions are pointed out in premises to be considered in the design of policies, measures and institutions for the protection of traditional knowledge.

In indigenous peoples their knowledge is intrinsically articulated with their lifestyle, therefore, right to self-determination is relevant in the design of mechanisms to preserve and protect traditional knowledge. To answer questions about what is understood by “protection” and what should be protected requires the autonomous, active and full participation of peoples according to their customary law and traditions. Thus, the communities and peoples themselves should decide on their priorities for their permanence and strengthening from their perception which is to “Define and implement our own priorities for the economic, social and cultural development and environmental protection based on our traditional culture, knowledge and practices, and the implementation of our inherent right to self-determination” (Rio+20 Indigenous Peoples International Declaration on Self-Determination and Sustainable Development 2012). As recognized in the United Nations Declaration on the Rights of Indigenous Peoples (Arts.3, 31 and 32, UNDRIP) the exercise of self-determination is when people can decide the level of interaction and adoption of practices, products and technologies for their political, cultural, economic and social development.

In this regard, protection of traditional knowledge is a fundamental right of indigenous peoples as an integral and substantive part of their lifestyles as indigenous experts from the region like Rodrigo de la Cruz (2005) have specified. The above premise was reaffirmed in the Rio+20 Indigenous Peoples International Declaration on Self-Determination and Sustainable Development (2012) stating that: "self-determination is the basis for Good Living of our peoples", this makes that ensuring land rights, land management and building dynamic community assets become a top priority as local economies are the ones that ensure sustainable livelihoods and community solidarity and are the basic components of ecosystem resilience".

UNDRIP recognizes explicitly in its Art. 31 the right of indigenous peoples to control and protect their traditional knowledge, cultural expressions and manifestations of their science, technologies and cultures. It also includes the right to "maintain, control, protect and develop intellectual property over such cultural heritage, their traditional knowledge and traditional cultural expressions" (Art. 31). Although it is part of the so-called soft-law, with no legally binding force, UNDRIP is part of the mandatory legal framework in countries such as Bolivia, which adopted Law N° 3760 on November 7, 2007, and in the legal systems that integrate UNDRIP provisions as part of the constitutional regulation because they represent fundamental human rights. Additionally, its adoption by the General Assembly of the United Nations signed by 143 countries and subsequently by countries that abstained or were initially opposed, place UNDRIP as a necessary reference in the design of protection systems.

The Nagoya Protocol negotiations resulted in significant recognitions in the international forum of the CBD since under its framework local and indigenous communities are collective subjects of interest. The Nagoya Protocol encourages countries to adopt legislative, administrative and policy measures to ensure that these communities are part of the benefit sharing derived from the use of traditional knowledge and genetic resources, according to national regulation (Art. 5, paragraphs 2 and 5). Regarding traditional knowledge related to genetic resources it reiterates the relevance and necessity of taking into account customary law and community protocols (Art. 12, paragraph 1). It also reiterates guidelines previously established at regional level, for example in Decision 391 of 1996 which states that the need of the Nagoya's Protocol implementation does not restrict customary exchange of genetic resources and traditional knowledge (Art. 12, paragraph 4).

Summarizing, provisions of the Nagoya Protocol specify the obligations of the parties regarding the rights of indigenous and local communities within the CBD's scope. For this reason, it's importance lies in not contradicting the rights contained in the UNDRIP and allows for an interpretation that can direct the action of signatory countries; however, since it is a binding instrument, the language used "each party shall take legislative, administrative or policy measures, as appropriate" and provide compliance "in accordance with domestic legislation" introduces a wide range of uncertainty as for the effective compliance of these obligations by the states.

2. Challenges to establish the subject of rights

Plurality of ancestral peoples and communities, their different historical backgrounds and different levels of interaction with a prevailing social organization become issues that pose enormous challenges to specify the subjects of rights. The definition adopted by international instruments set a precedent in the ILO's 169 Convention of 1989. This definition highlights objective factors that refer to the distinction between tribal and indigenous peoples. The first refer to communities with specific social, cultural and economic conditions and that are also completely or partially governed by their own customs and traditions.

Former colonies of indigenous peoples are those who have ancestral ties to human groups in a territory to the arrival of the colonizer, retaining their own social, economic, cultural and political institutions. Equally, the definition adopted by the 169 Convention includes an essential aspect concerning indigenous or tribal awareness or self-recognition since for their own indigenous peoples the question of who is indigenous and the criteria for their recognition always has political implications (Corntassel 2003). Thus, the ILO's 169 Convention of 1989 in its Paragraphs 1 and 2 apply:

1. a) To tribal peoples in independent countries whose social, cultural and economic conditions distinguish those from other sections of the national community, and that are also completely or partially governed by their own customs and traditions or by a special legislation.
- b) To the peoples in independent countries, considered indigenous on account of their descent of populations that inhabited the country, or a geographical region to which the country belonged at the time of conquest or colonization, or at the establishment of current country borders and whatever their legal status retain some or all of their social, economic, cultural and political institutions.
2. Awareness of indigenous or tribal identity should be considered a fundamental criterion for determining the groups to which the provisions apply.

The CBD adopts the term indigenous and local communities but in the preamble refers to local communities and indigenous populations embodying traditional lifestyles on biological resources. Art. 8(j) specifies one of the commitments of member countries; the CBD refers to local and indigenous communities embodying traditional lifestyles on biological resources relevant for the conservation and sustainable use of biodiversity and its components. It also recognizes the close dependence of communities on biodiversity and the convenience of equitably benefit sharing derived from the utilization of traditional knowledge but it does not include an operational definition. Even so the term indigenous and local communities, was adopted in the instruments developed by the CBD and the Cartagena Protocol (2000) and the Nagoya Protocol (2010).

The importance of the efforts by the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC) and the WIPO lies in a greater determination, indicating that the use of the term "indigenous and local communities" in the CBD refers to "communities identified from yesteryear with the lands and waters in which they live or have used in accordance with their traditions" (Secretariat of the Permanent Forum on Indigenous issues

2004; Secretariat of the Permanent Forum on Indigenous Issues 2006). Specifying even further the notion of local community, it is stated that it refers to “the human population living in an area that is distinguished by its own ecological characteristics and whose livelihood depends completely or partially, directly to the goods and services that biodiversity and the ecosystem provide. The traditional knowledge of this population comes from a relationship of dependence regarding activities such as: agriculture, fishing, grazing, hunting and harvesting to name a few” (UNEP-CBD 2005: 2). Other instruments like FAO International Treaty on Plant Genetic Resources for Food and Agriculture also use the term “indigenous communities” and “local communities”, but do not provide an explicit definition and they do recognize the contribution made by these communities in terms of plant species for food and agriculture (Art. 9.1).

The Andean region advances in defining the community's holders of rights on indigenous, traditional or ancestral knowledge. Decision 391 of 1996 of the Andean Community of Nations (CAN), includes the definition of indigenous, African American or local communities as a: “human group whose social, cultural and economic conditions distinguish them from other sections of the national community, and that are also completely or partially governed by their own customs and traditions or by a special legislation and that whatever their legal status retain some or all of their social, economic, cultural and political institutions”; this definition is similar to the one of the 169 Convention of 1989 while eliminating the subjective component. The subject of protection in the Andean legislation includes afro descendants and local communities, with the first including populations that were moved to the mainland as slaves in the colonial period. Additionally, the definition of the Andean law accepts the expression “local communities” of the CBD, reaching populations that without being indigenous have a relation with biodiversity resources and peasant communities whose indigenous identity was blurred in most cases by integration processes and land reforms.

In each historical-cultural context the collective subjects intended to be protected can be more complex. In Bolivia for example, when the multinational state was established, the new Constitution explicitly recognized native Nations and Indigenous Peoples and peasants, including the term “intercultural communities” when referring to peoples from the west of the country who migrated to the east under a policy of expanding the agriculture frontier in 1960's. Additionally, the Constitution of 2009 recognizes the same rights to Afro Bolivian communities. When considering the historical context in multinational states such as Bolivia, the accuracy of the legal subject from a bio cultural approach is relevant if one considers that the various indigenous peoples account for more than 40% of the population (INE 2012). The accuracy of the subjects of protection will be an element for political decisions when developing sui generis regimes, as detailed in Peru's protection regime.

6. Protection under intellectual property rights and *sui generis* regimes

The diverse and complex issues surrounding the discussion of a protection system of traditional knowledge were initially undertaken under the WIPO's framework as technical issues to be explored and creating the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC). IGC's exploratory activities initiated in 2001 include various governmental, industrial, academic, indigenous and non-governmental perspectives. Precisely, given the link to the negotiations in the CBD and the nature of the WIPO, the IGC took an initial defensive approach from intellectual property on issues of access and benefit sharing derived from the utilization of genetic resources, protection of traditional knowledge and folklore expressions. Thus, the conceptual approach that guides IGC's activities differentiates traditional knowledge from traditional cultural expressions or folklore expressions. Within the reference framework of intellectual property both groups are seen as economic and cultural assets and are subjects of protection.

In developing their analysis the IGC understands traditional knowledge as "[...] dynamic and constantly evolving knowledge created in a traditional context, collectively preserved and transmitted from generation to generation and including, among others, specialized knowledge, skills, innovations, practices and learning that survive in genetic resources" (WIPO 2012a: 4). Anyway, there is no consensus within the IGC on patentable subject matter and the latest versions of the document "Protecting Traditional Knowledge: draft articles", developed by the Secretariat includes two definitions of traditional knowledge (WIPO 2012b; WIPO 2013).

Nowadays, it is accepted that traditional nature does not refer to the content of knowledge but to its context and the collective nature shows its connection with the distinctive lifestyle of a community or people. Thus, for the IGC indigenous knowledge is considered as part of a larger universe of traditional knowledge (WIPO 2012a). The connection between traditional knowledge, lifestyle and cultural identity of indigenous peoples who deserve protection is not new in the IGC debates: "it may be necessary for knowledge to have an intergenerational nature, be objectively linked to the community of origin and maintain a subjective association within that community so that it is part of its identity" (WIPO 2008: 5). From this point of view, traditional knowledge is not restricted to only the one linked to genetic resources but it also includes any technical scope. Knowledge related to biodiversity is just one example which seeks to be protected as specified in the second part of one of the options for definition that states: "traditional knowledge is also the knowledge related to biodiversity, traditional lifestyles and natural resources" (WIPO 2012b: 8).

The scope of IGC fixes intellectual property as required by the operational concept of protection, differentiating its scope from other international instruments as de CBD, the UNESCO Convention for the Safeguarding of Intangible Cultural Heritage of 2003 and the UNESCO Convention on the Protection and Promotion of the Diversity of Cultural Expressions of 2005. In this context, protection is the safeguarding of traditional knowledge and traditional cultural expressions against unauthorized

use

or unfair exploitation distinguishing positive protection and preventive protection. For these reasons, the first seeks to prevent unauthorized use by third parties; it also includes direct control and exploitation of traditional knowledge by the community itself. Meanwhile, the second seeks to prevent the granting of "property rights unfounded or illegitimate on the subject matter of traditional knowledge and related genetic resources" (WIPO 2008:6; WIPO 2012a: 36).

Under the framework of intellectual property, finding solutions starts from considering that if used for undue monopolization and privatization of indigenous knowledge, their institutions can be improved to avoid it. Nowadays, patent-related measures such as disclosure of origin and certificates of origin are included and the adoption of similar measures is suggested regarding the granting of plant certificates (Tobin 1996; Mgbeoji 2006). Minimum documentation was expanded regarding the patent law through the Patent Cooperation Treaty (PCT), trying to resolve the availability of publications on traditional knowledge at the reviewing phase of state of art or technique. Also in 2006, a category of subjects related to traditional knowledge were included in the International Patent Classification (WIPO 2008); however, with its potential adjustments and additions, limitations of intellectual property to protect traditional knowledge and its cultural expressions were recognized (OMPI 2012c).

Because of the particular conditions of creation, transfer and use of traditional knowledge it has been suggested that its protection requires the design of unique and special system or *sui generis* system. The design of *sui generis* systems is necessary since the notions of private property and individual intellectual property when related to traditional knowledge and biodiversity elements object free trade and its distribution in traditional cultural contexts (Posey 2002). Control and restriction to access and use of traditional knowledge are not relevant except when using sacred plants in ceremonies and spiritual practices that require training and qualification for its handling.

Currently various indigenous peoples and local communities that interact with biodiversity face a context that pushes for industrial and commercial use of their knowledge. The prevailing view regarding intellectual property seeks to protect traditional knowledge but responds to the increasing activity of private initiatives and research institutes and to the difficulty of controlling its use. Nemogá-Soto (2013a) conducted an analysis in Colombia, during 1991-2010, showing that research programs on genetic diversity and biodiversity policies were defined without acknowledging the active role and the rights of communities and peoples that constitute the ethnic and cultural diversity of the nation. Cooperation agencies such as UNCTAD identify indigenous knowledge as a valuable resource that could be used for development and trade with economic outcomes for its owners (Bhatti 2004). Twarog (2004) suggests the need of a comprehensive national assessment to preserve, protect and promote traditional knowledge anticipating an eventual disposition of some communities to participate in the commercialization of their knowledge or of its cultural expressions.

Currently, commercialization of traditional knowledge and its products is an option that some communities take over in inequitable conditions. It is in this context that control over their knowledge, innovations and practices as well as the use of intellectual property tools as collective brands, denomination of origin and geographical indications, and certificates of origin among others, can play a role to ensure a fair benefit sharing (Tobin 1996; Downes and Laird 1999). In this case it would not be about a *sui generis* regime but about the use of intellectual property tools to improve the bargaining capacity and position of communities who choose to develop marketing relations.

From an indigenous peoples perspective the possibility of commercial transactions on their collective knowledge would only be a complementary option but it may not be the central reference point for protection and conservation of their traditional knowledge, unless communities radically transform their collective and traditional lifestyle. Meanwhile, under the economic framework in which protection alternatives develop through intellectual property rights, preservation of the different lifestyles of indigenous peoples and the indefinite practice and renew of their knowledge in the community are not priorities. Preservation of knowledge, traditional knowledge and practice demand the design of *sui generis* protection measures without losing sight that full conservation requires bio cultural approaches that incorporate indigenous worldviews.

The document "Protection of Traditional Knowledge. Draft Art.s" was submitted to the WIPO's General Assembly in 2012, framed in the development of one or more binding international instruments to protect genetic resources, traditional knowledge and traditional cultural expressions (WIPO 2013). The joint draft IGC-WIPO is a work document generated under the mandates of WIPO's General Assembly that includes alternative wording and the facilitators' reasoning on the reach and systematization of the draft. To date, alternative texts still show strains between comprehensive protection of traditional knowledge and a functional protection for its marketing purposes.

In the development of IGC's deliberations "political objectives" and "general guiding principles" were incorporated in the document WIPO/GRTKF/18/5 Prov. (WIPO 2010), including elements such as the acknowledgment of the intrinsic, spiritual and scientific value of traditional knowledge when: recognizing that traditional knowledge systems have equivalent scientific value than other knowledge systems (whereas i); calling to respect traditional knowledge systems, their contribution to science and technology, food security and sustainable agriculture (whereas ii); recognizing the distinctive nature of traditional knowledge systems and leaving open the possibility that protection systems belong to that nature (whereas v), and ratifying the consensus regarding the vocation to enforce the Prior Informed Consent (PIC), the MAT and preventing misappropriation of traditional knowledge (whereas vii).

The aforementioned document includes, although they are not consensual texts: stopping the grant or exercise of intellectual property rights over traditional knowledge and genetic resources by creating digital libraries of traditional knowledge (whereas xiv) and demanding the disclosure of the source and country of origin of resources, evidence of PIC and benefit sharing conditions (whereas xiv); the text also mentions: collecting the strain in sectors that reiterate the value of the concept of public domain on traditional knowledge (whereas vii).

In general, the document promotes the connection of communities with the commercial use of traditional knowledge for economic development and the marketing of by-products from traditional knowledge. The link between traditional knowledge and its by-products with economic development seeks to ensure relations of the community with different market options (WIPO 2013); however, this option is conditioned to be consistent with the right of communities' holders of knowledge to freely define their economic development.

The IGC negotiation process and outcomes will have a great influence on the development of protection regimes, even though its development as an international instrument is ongoing. Anyway, at country level it is necessary to advance on debates to improve the comprehensive protection options that will recognize historical contexts and the nature of biodiversity in each case. For this purpose, the background of the Andean Community of Nations (CAN) should be examined, oriented to establish a *sui generis* regime.

The elements required for the CAN's *sui generis* regime proposal emphasizes the knowledge, innovations and practices of indigenous peoples related to biodiversity but also refer to cultural and folklore issues (Cruz *et al.* 2005). The proposal includes ancient knowledge since it comprises the wisdom of indigenous peoples according to their worldviews. The elements emphasize "the wide range of traditional knowledge, innovations, and practices of indigenous peoples related to biodiversity and cultural and folklore issues" (Cruz *et al.* 2005: 7). Among the alternatives considered by Cruz and colleagues (2005) for a *sui generis* protection are:

- i. A *sui generis* protection regime of collective and comprehensive knowledge without further interaction with the intellectual property right.
- ii. A *sui generis* protection regime for traditional comprehensive and collective knowledge as a result of combining intellectual property rights and knowledge systems of indigenous peoples.
- iii. Protection through national standards.
- iv. Protection of traditional comprehensive and collective knowledge through customary law.

The proposed elements promote the adoption of *sui generis* protection Andean regime for comprehensive and collective traditional knowledge, innovations and practices of indigenous peoples on the basis of customary law and cultural practices.

In support of this action it should be stated that: "Organizations of indigenous peoples have agreed that a *sui generis* regime could be the ideal mechanism given the nature of traditional comprehensive and collective knowledge as its collective nature and intergenerational practice. However, a protection measure through current intellectual property rights does not solve the underlying problem even by incorporating new elements, i.e. the very nature of the given knowledge does not ensure its continuation and dynamics." (Cruz *et al.* 2005: 25).

In a later text on possible elements for a *sui generis* regime of the General Secretariat, Andean Community (2009: 3), the general objective is "value and strengthen the knowledge systems of indigenous peoples and Afro American and local communities, and prevent misappropriation of this knowledge and its various tangible and intangible cultural manifestations". The proposal retakes elements from the intellectual property field, establishing the scope of application on traditional knowledge linked to ecosystems management and the use of biodiversity resources, and traditional cultural expressions; considering guarantees such as PIC, confidentiality and laws against unfair competition, national and local records, agreements, contracts and licensing agreements (General Secretariat Andean Community 2009). It also includes among the positive protection mechanisms and instruments, tools of intellectual property such as collective brands, geographical indications and copyright.

The document of the General Secretariat of the Andean Community (2009) aforementioned has not yet been formally adopted and is part of a limited perspective from the intellectual property scope for the development of a *sui generis* protection regime, unlike the comprehensive protection option and culturally appropriate. Regarding policy decisions it seems relevant to retake the work groups of indigenous experts, take into account the elements contained in the document of the General Secretariat but focusing the debates and works from a bio cultural diversity perspective with a vocation to integrate indigenous worldviews.

In general the approach of bio cultural diversity, the acknowledgement of concepts as the Good Living and the protection initiatives under the notion of "collective bio cultural heritage", are distinguished because they highlight the relevance and the need to work with concepts that would give scope to indigenous worldviews. Countries of Latin America and the Caribbean are noted for leading innovative approaches for the use of biodiversity and proposals to establish access regimes, combat piracy and introduce modifications to the patent system. Likewise, proposals that start out from the recognition of the importance of bio cultural diversity for the design of a *sui generis* system for the sake of a comprehensive protection of traditional knowledge could be developed, corresponding to self-determination and cultural affirmation of indigenous peoples and local communities. Access and record regimes that exist or that are in debate in some countries can be complementary to a comprehensive protection regime, but since they are directly or indirectly framed in intellectual property rights institutions they could be limited in their scope. Cases of collective knowledge records in Peru become one of the most consolidated experiences in the region for the protection of collective knowledge.

7. Record of collective knowledge in Peru

7.1 Background of the process

The development, discussion and adoption process of the protection mechanism of collective knowledge in Peru took at least six years since from the adoption of Decision 391 in 1996 consultation groups were established formed by representatives of government, the academy, indigenous communities and NGO's who brought about the development and adoption of a law for the protection of traditional knowledge (Tobin and Swiderska 2001; Álvarez 2008; Ruiz 2010). In 1997 Law 26839 on Conservation and Sustainable Use of Genetic Resources recognized that knowledge, innovations and practices of indigenous peoples related to biodiversity are part of their cultural heritage and they have the right to decide on their use. The development of the first drafts of a possible legislation was structured from meetings with leaders of indigenous communities, representatives of neighboring countries as well as in seminars and international meetings sponsored by the National Institute for the Defense of Competition and the Protection of Intellectual Property (INDECOPI) and the WIPO (Pacón 2004). On October 21, 1999 INDECOPI published the "Proposal for a Protection Regime of Collective Knowledge of Indigenous Peoples and Access to Genetic Resources" (Resolution 0322-1999-INDECOPI/DIR) and in 2000, at least two drafts of the proposal were officially published by INDECOPI (2000). Two years later, Peru adopted Law N° 27811 in August, 2002 for the Protection of Collective Knowledge of Indigenous Peoples related to Biological Resources.

Throughout the government's initiative on a "Proposal for a Protection Regime of Collective Knowledge of Indigenous Peoples and Access to Genetic Resources", the participation of organizations and indigenous peoples were not considered as procedures of prior consultations. Indigenous participation was lower in the development phase (1996-1998), higher in the consultation phase (1998-1999), and significant in the post-publication (1999-2000) (Tobin y Swiderska 2001). Tobin and Swiderska (2001) pointed out that the governmental initiative considered regulatory voids on traditional knowledge that became evident during the negotiations of an agreement for the Cooperation Program for Biodiversity in Peru which included: the University of Washington; Sarle & Co. (a Monsanto subsidiary); representative local and national organizations of the Aguarunas in the Amazon and the Confederation of Amazonian Nationalities of Peru (CONAP); the Natural History Museum of the National University of San Marcos, and the University of Cayetano Heredia in Peru. Associated collective knowledge are diverse and highly valued in Peru, given the existence of 1.786 Amazonian indigenous communities of 60 ethnic peoples according to the 2007 Census, while there are Afro Peruvian and peasant communities that interact with the country's biodiversity.

When INDECOPI's publication was released, a Working Group on Indigenous Peoples (GTPI) was created and it was composed by governmental agencies on indigenous affairs and indigenous organizations in order to achieve a nationwide broadcasting (Tobin y Swiderska 2001). Participation activities continued with the enactment of the law, and Ruíz (2010) states that during the training activities and the implementation of Law 27811, representatives of indigenous organizations participated in the definition of application forms and in the adoption of the criteria of free procedures for records and infringement complaints.

The Peruvian initiative was not limited to the issuance of a law; it was part of the government's response and was supported by sectors of civil society to enforce the country's rights over genetic resources. The direct involvement and leadership of INDECOPI in this experience are relevant, correlating with the emphasis and objectives of the record system demarcated by institutions of intellectual property. The establishment of inter-agency work groups convened by state entities, NGO's, researchers and some indigenous organizations on the development of the initiative is a characteristic feature of the participatory approach of legislation on this subject in Peru. The dynamics on the collective knowledge protection issue also influenced internationally with the positions that the official delegation of Peru submitted to the CBD, WIPO and the World Trade Organization (WTO), with the Report of the *ad hoc* Commission as an example, led by INDECOPI in the fifth Intergovernmental Committee Meeting on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore of WIPO (2005).

The Peruvian governmental strategy included the creation of a National Commission for the Prevention of Bio Piracy by Law 28216 of 2004 on Protection on Access to Peruvian Biodiversity and Collective Knowledge of Indigenous Peoples. The multi-sectorial Commission is composed of government agencies, government and non-government and private organizations, intended to "identify and follow up on requests for patents granted abroad related to biological resources and collective knowledge of indigenous peoples [...]" (Art. 4, c, Law 28216); it also complements the protection regime for collective knowledge established by Law 27811.

The Peruvian initiative had international favorable contexts encouraged by commitments on intellectual property under the WTO and by the introduction of access regimes under the CBD. At the same time the need to update the laws on intellectual property in Andean countries and the imposition of a minimum protection on intellectual property matters generated a reform process. The development and adoption of Decision 345 of 1993 on the Common Regime for the Protection of the Rights of Plant Breeders' set the direction for CAN countries and it was intended to protect the rights over homogenous, stable and distinct plant varieties obtained by scientific methods. The measure itself in Andean countries gave priority to the interests of breeders but especially to exporters that needed to ensure a minimum protection to the rights of holders of plant varieties used in the international market, for example the flower industry in Colombia.

Results of Decision 345 introduced a protection regime for plant breeders but neglected the need to develop a *sui generis* regime to protect innovations, knowledge and practices of indigenous peoples from the region; leaving out the protection of rights of indigenous and local communities who for centuries domesticated and cultivated them through local and ancestral relatives and that served breeders as base material for new plant varieties and to obtain exclusive rights. Decision 345 granted rights to whom obtained varieties through scientific procedures but not to indigenous and local communities that obtain their varieties through traditional methods as stated in Art. 4: "Member Countries shall grant breeders' certificates to people who have created plant varieties when they are new, homogenous, distinct and stable and have been assigned a name that constitute their generic designation.

For the purposes of this Decision, to create means obtaining a new variety through the application of scientific knowledge for the genetic improvement of plants". As a result of the debate about this regime and its implications a transitory regulation was included establishing a Common Access Regime on Biogenetic Resources under the CBD (Clause 3, transitory provisions, Decision 345).

In the context for recognizing sovereign rights over genetic resources CAN countries were pioneers in developing a common access regime highlighting the presence of ecosystems that transcended their political and administrative borders. The establishment of Decision 391 of 1996 recognized the close interdependence of indigenous, Afro American and local communities with biodiversity and the right to decide on the Access to their knowledge (Art. 7). Years later, Decision 486 of 2000, again reaffirmed the obligation to disclose the origin of genetic resources and traditional knowledge regarding intellectual property when inventions are directly or indirectly related (Art. 26 literal h, i, j).

Decision 523 of 2002 on the Regional Strategy of Biological Diversity and Decision 524 which established a Working Group on Indigenous Peoples traditional knowledge were again referred to but without developing a protection regime. Debates on regulations and work plans in the Andean region on access to genetic resources created a suitable environment for protection methods for collective knowledge related to biodiversity yielding in Peru unlike other Andean countries. Internationally, the Fifth Conference of the Parties in 2002 (COP 5, Decision V/16: Art. 8j) required the support of the development of records of traditional knowledge, innovations and practices of indigenous and local communities (Convention on Biological Diversity 2000). In the case of Peru, the record system is part of a national strategy tending to counter the loss of control of traditional knowledge because of economic, social and cultural processes; since this is the legal and policy instrument directed to promote, value, diffuse and protect communities' collective knowledge (Ruiz 2010).

7.2 Objectives of a record of collective knowledge

In Peru the primary objective is to establish a special protection regime for collective knowledge of indigenous peoples related to biological resources (Art. 3), establishing a system as a defense mechanism to prevent the granting of intellectual property rights on inventions derived from these, particularly distorting the newness in patent applications (Art. 5, literal f). In addition, the record is a mechanism that can facilitate transactions among potential users of collective knowledge on biodiversity and their suppliers. Therefore, an institutional base is established to ensure that communities that provide knowledge participate in the benefit sharing derived from their use.

The Peruvian regime seeks that the use of collective knowledge is done with the PIC of indigenous peoples, as well as under a fair and equitable sharing of benefits derived from their use. In a broader sense, the system seeks to promote respect, preservation and application of collective knowledge; strengthen and build capacities of communities; motivate its use for the benefit of indigenous peoples and humanity (Art. 5, literal a, e, d). These objectives are limited to the record system covering collective knowledge but reaches over practices and innovations of indigenous peoples related to biodiversity as stated in the CBD

Art. 8(j) of the CBD includes respect and preservation of knowledge, innovations and practices of indigenous and local communities who incorporate lifestyles relevant for the conservation and sustainable use of biodiversity but also includes as a goal its wider application providing that benefit sharing from its use is equitable. The Peruvian record system focuses the documentation of collective knowledge on biodiversity emphasizing in the prevention of illegal granting of patents.

7.3 Scope and limitations of the record system

Records are by nature restrictive in scope so they can not cover all intellectual and cultural expressions of a community or peoples. The record system in Peru does not cover other kind of knowledge different from the ones related to biodiversity, it differs from the legal protection regime applied in Panama that focuses on inventions, models, drawings and designs, innovations contained in images, figures, symbols, graphics, petroglyphs and other details as well as cultural, historical, music, arts elements, artistic expressions and all manifestations suitable for commercial use (Legislative Assembly of Panama 2000). While the Panamanian system focuses on objects that are cultural expressions of indigenous peoples (Presidency of the Republic of Panama 2001) the Peruvian one covers collective knowledge related to the use of biodiversity.

The Peruvian system is structured in the context of intellectual property and its record of collective knowledge works in combination with other instruments as licensing agreements for commercial use, trade secrets and competition regulation (Art. 6). PIC of corresponding indigenous organizations must be obtained when access to collective knowledge is for scientific, commercial or industrial application and if this access has commercial or industrial purposes; in addition, a licensing agreement is required whose minimum contents are also legally established (Arts. 6 and 7). Peruvian Law introduces the possibility for communities to receive compensation for the use of collective knowledge found publicly accessible or placed in a public domain in the last 20 years (Art. 13).

To the extent that record of collective knowledge has declarative effects its implementation does not override the rights of other peoples. Knowledge can belong to several communities (Law 27811, Art. 10), for example, in a community the use of some plants has spiritual connotations that are not shared equally with another. The system provides that in cases of differences between indigenous peoples, customary law and traditional forms of conflict resolution can be applied (Art. 46), applying this provision in all discrepancy cases under the regime's application. A particular situation would be the obligation to inform the largest number of indigenous peoples holders of knowledge that is being subject of negotiations of licensing agreements by indigenous organizations and the obligation to take into account their interests and spiritual, cultural values or religious beliefs (Art. 6).

The obligation does not include notifying communities from neighboring countries; therefore, for the ones sharing ecosystems it is important to provide mechanisms of mutual notification identifying the entities responsible for conducting it. So, the situation is relevant for indigenous peoples, whose ancestral lands were divided by political administrative borders, keeping common ecosystems and biodiversity incorporated into their customs, traditions and culture. Countries from the Andean region could design mechanisms to notify about access applications and search for consensus, especially among communities that are separated by national borders drawn in their territories.

The Peruvian record system is a defensive protection (Art. 16), whose goal is the availability and use of public information that could be used by intellectual property offices to establish the state of art in the field of innovation; therefore, if it is defensive it seeks to detract the claims of novelty in patent applications on innovations based directly or indirectly on traditional knowledge. Among the elements of positive protection of the records of confidential collective knowledge, issues related to industrial or business secrets are enshrined such as the protection against disclosure or breach of confidentiality reserve (Art. 42). Thus, communities assert their rights over knowledge registered and have additionally compensatory actions against users who do not follow access protocols provided in the regulation or that breach confidentiality obligations (Art. 43).

It should be noted that the emphasis of the Peruvian system is not the establishment of exclusive rights but to specify the existence of certain collective knowledge in a specific community and to prevent its misappropriation by third parties. Communities that record confidential knowledge do not receive protection as exclusive holders as others may share the same uses and register them later; however, at the request of access to registered knowledge, the communities are the ones that register it and the ones who can grant or deny such access by negotiating licensing and ensuring the benefit sharing derived from their use. At the same time the record system of collective knowledge does not limit the direct use by communities that have it or the traditional exchange between them. Even when licensing has been granted by indigenous peoples on certain knowledge, these cannot limit the granting of others over the same knowledge by other communities (Art. 32).

7.4 Collective knowledge as an object of protection

Peruvian Law focuses on collective knowledge of indigenous peoples and explicitly excludes the one who could belong to an individual (Art. 10), since it is understood that it has protection in all available forms of intellectual property. In practice, members of a community do not produce knowledge in isolation, but rather receive them from others or as a result of interactions with members of their community. In the empirical component of the use of medicinal plants, traditional doctors test their procedures, test those used to treat diseases in the community and get answers and information from patients on results that corroborate its effectiveness in proceedings. The idea of an isolated individual inventor does not appear in indigenous societies as the individual creator of knowledge is a concept developed during the Renaissance and consolidated in capitalist societies focused on the individual as the core of property rights.

For this reason, the image of the isolated inventor persists in modern society despite the technological revolution that transformed the work of individual researchers in work groups and teams of researchers, often located in different places but researching on the same product or technological application.

Regarding the beneficiaries, some systems leave open the possibility of benefits for individual holders of traditional knowledge (WIPO 2011); there is also the possibility of recognizing the rights to a governmental authority, provided that the income derived from their use is transferred to educational programs for sustainable development, national heritage and social or cultural welfare. According to the extent of Peruvian Law, it is intended to prevent the record of collective knowledge as an individual, after going through the requirements established for its application (Art. 20). In this regard, it is anticipated that indigenous peoples be represented by their own organizations according to their traditions (Art. 14) and as subject of protection.

7.5 Peruvian regulation and the subject of rights

Peruvian regulation settles the delimitation of the subject who receives protection in a quite flexible and broad way defining indigenous peoples for purposes of the protection system of collective knowledge as native peoples prior to the creation of the national state with their own culture and land; incorporating the subjective element of self-recognition. It also explicitly includes peoples in voluntary isolation and peasant and native communities; even though the definition defines the scope in the first paragraph, then it indicates that indigenous is synonymous with original, traditional, ethnic, ancestral, native or other words (Art. 2, Law 27811).

Under the Peruvian regulation the definition of indigenous peoples does not become an obstacle to include other communities interested in the protection system of collective knowledge and the operation of the record system. In developing the regulation, the representation of Andean, Amazonian and Afro Peruvian peoples is recognized both in a Management Committee of the Indigenous Peoples Development Fund (Art. 39), as in the specialized Council on protection of indigenous knowledge (Art. 66). On April 2011, the first meetings with indigenous peoples for the creation of the Committee were held (Mescoco 2011).

7.6 Rights of Indigenous Peoples

In Art. 1 and consistent with Art. 7 of Decision 391, the Peruvian regulation recognizes “the right and the power of indigenous peoples to decide over their collective knowledge”; although registration does not constitute rights when indigenous peoples register their knowledge they acquire protection against undue “disclosure, acquisition or use of such collective knowledge without their consent or in an unfair manner” (Art. 42), provided that it is registered in the confidential record. Actions against infringement may be initiated ex officio by INDECOP or by action brought by the wronged people. In cases of utilization that are contrary to the provisions in the record system, organizations of indigenous peoples affected by such utilization can exert actions claiming ownership and indemnification (Arts. 42, 43, 45).

7.7 Collective knowledge record system

The Peruvian Law establishes a system composed by records, licensing, industrial secrets and a compensatory mechanism for using traditional knowledge related to biodiversity. Record of collective knowledge includes one public, one confidential and eventually one local (Art. 15). In the Public Registry, publicly accessible knowledge is integrated since it was previously disseminated and published with or without the consent of the communities and regardless the circumstance in which it was published. Knowledge included in such registration is based on available bibliographic information.

The Confidential Record is composed by collective knowledge reported as such by indigenous peoples and communities to the national authority of intellectual property; also they come at a request of representatives organizations of communities or peoples. Similarly, the Law provides for the establishment of local records of collective knowledge according to uses and customs and communities may request technical assistance from INDECOPI.

The number of records increase steadily over time with 219 records of collective knowledge in 2009 (Ruiz 2010) and in October 2012 they went up to 1081 records including knowledge in public records; even though the majority (60%) were knowledge and information not published. At the same time in the same year 2012, INDECOPI received 1594 applications to record collective knowledge (INDECOPI 2012).

The management of the systems shows that records processes are complex because of validation procedures since without identification and verification of the involved biological resources these are unsound. Thus, additional costs should be considered in the collection, transportation, conservation and identification of specimen processes, generating difficulties for the communities but without their related scientific identification it is impossible to grant the corresponding record.

Licensing provided as part of the system have a minimum content defined by law and always proceed if a third party seeks access to confidential collective knowledge for scientific, commercial or industrial purposes (Art. 27). They must be recorded in Castilian and native languages, if applicable, and granted for a period between one and three years; it also explicitly provides for compensation including no less than a 5% of the value of gross sales of products as a direct or indirect result of the use of indigenous knowledge (Art. 27, literal c). In 2013 applicability studies were conducted and a possible flexibilization of rates on royalties set by law (Ministry of Environment and Sustainable Development 2013). Among the requirements it is expected to obtain the PIC rendering mandatory for the user to provide initial and periodic information on the applications and what will be done with the indigenous knowledge; for this reason it is mandatory for licensing agreements to meet the minimum legal requirements and be registered with INDECOPI under confidentiality guarantees (Arts. 26 a 28).

In the future it is expected that users of publicly accessible knowledge negotiate compensations for its use with communities and peoples that adopted them originally. In this case it is expected that users pay for using information that even though it can formally be restricted is physically available. In this case it is not mandatory to register the licensing agreement with INDECOPI, making it difficult to measure the impact of this provision (Ortega, 2013).

Peruvian regulation includes as a supporting feature the trade secret figure applied to collective knowledge even when it is less relevant than the descriptions of the record's operation. In this regard, communities who document their knowledge in the confidential record acquire protection against "the disclosure, acquisition or use of such collective knowledge without their consent and in an unfair manner to the extent that this collective knowledge is not of public domain". In the same way it incorporates the protection against the disclosure by third parties who breach the obligation of discretion or confidentiality (Art. 42).

The compensatory mechanism for the use of traditional knowledge takes shape in the establishment of an Indigenous Peoples Development Fund (FDPI) same that was created with technical, economic and financial autonomy and it is intended to support the comprehensive development of indigenous peoples through the financing of development projects. The participation in economic resources for projects does not need applicant communities to document their knowledge in the record system. In any case, the granting for project funding is done through the Administrative Committee created on June 2011, composed by five representatives of indigenous organizations and two representatives of the National Commission of Andean, Amazonian and Afro Peruvian Peoples (Ministry of Environment and Sustainable Development 2013).

The law provides that the Indigenous Peoples Development Fund is financed with resources from the national budget, international technical cooperation, donations and penalties provided by law for violations of the rights of indigenous peoples on their traditional knowledge. A specific income source for the Fund is the percentage of economic benefits from royalties of gross sales, not less than a 10%, and the result of products developed directly or indirectly from collective knowledge not available in the public domain. Additionally, percentages for gross sales of products developed from knowledge that will be in public domain in the last 20 years are expected (Arts. 8 and 13, Law 27811); however, because of the recent creation of this Fund there is no information about its operation and performance.

7.8 Record content and ABS

The record content is determined by the scope and objectives of the regime that emphasizes in the mechanism as a tool to prevent bio piracy cases under the fair and equitable benefit sharing derived from the use of knowledge. Therefore, records are aimed to capture and document collective knowledge of indigenous peoples related to biodiversity, considering the context of intellectual property rights and access regulation.

Regarding the requirements to record collective knowledge, applications should be made by indigenous peoples or communities prior an internal consensus to record them providing a minute of collective or community agreement (Art. 20) and proceed through their representative organizations. Applications identify: indigenous peoples; the representative; biological resources related to knowledge and a description of knowledge or use intended to be recorded.

Given the objectives for detracting the claims of novelty in patent applications it is important to document the uses regarding specific components of biodiversity; requiring the identification of the biological resource thought samples, pictures, in order to perform their taxonomic classification and

assignment of the scientific name. At the same time, the suitability in identifying the biological resource is essential for all users of collective knowledge, especially when trying to develop industrial or commercial applications from it. The record application is accepted with the local or indigenous name but this information is irrelevant for a bio prospector as there is little interest in acquiring licensing if biological resources to which collective knowledge is related are not identified.

7.9 Record System Management

When managing a record system, aspects related with access conditions to information and manager's obligations must be defined. The main function of INDECOPI regarding the system is to keep and maintain the Record of Collective Knowledge of Indigenous Peoples as the Peruvian regulation established differential requirements on access conditions. Thus, according to the public or confidential nature of collective knowledge, access levels are broad and unrestricted in the first case directly fulfilling its defensive function; while in the second case access is restrictive and confidential consistent with the goal of benefit sharing derived from the use of knowledge.

Another contribution of the confidential record of collective knowledge is documenting the state of art, preventing the possibility of patents related to traditional knowledge. Access to the contents of this record could be restricted for its spiritual connotation or cultural value, considering the development of the powers granted to indigenous peoples and communities. Besides the centralized management of the public and confidential records by INDECOPI, regulation provides that local organizations can establish their own record; in this case its creation and operation should be articulated with the national record system and technically supported by INDECOPI.

When establishing the public and confidential records it is expected that the managing entity, INDECOPI in this case, act as guarantor of the relationship between potential users and communities holders of knowledge. Even the elements of the licensing agreement have minimum requirements provided they are recordable with INDECOPI (Art. 27). In this regard, INDECOPI's function is to keep a record of licenses as well as assessing the validity of the licensing agreements on collective knowledge of indigenous peoples.

Combination of Access types to the Peruvian record system corresponds to the conditions of communities and indigenous organizations, so the ones with sufficient capacity to establish community records and to negotiate licensing directly with potential users can do without a central administration. Otherwise it requires support and legal certainty for the system's operation because the communities will not be able to do it in isolation.

7.10 Traceability and monitoring of licensing agreements

The second additional provision of the Peruvian Law renders mandatory for the patent application of a product invention or processes developed directly or indirectly based on collective knowledge to attach a copy of the licensing agreement. Omission of the requirement is grounds for denial of the application or even nullity of an eventual granted patent. Thus, this regulation follows the guidelines of Decision 486 of 2000, regarding the requirements for patent applications and disclosure of origin of resources and traditional knowledge (Art. 26, paragraphs h, i, j).

The National Commission against Bio Piracy and INDECOPI interpret the regulations in force in order to recognize the rights of all parties involved, among them the Peruvian State, indigenous peoples, and businesses and researchers who develop innovation and products. The purpose is to implement a fair and equitable benefit sharing and recognition of rights, with an interest so the patents applicants regularize the access and observe the regulation on access at national and international levels. Rather than an exclusive defensive approach, INDECOPI and the Commission have focused lately on finding friendly approaches with potential offenders before initiating any opposition actions, making applicants voluntarily withdraw the respective application (Valladolid Pers. com. 2013).

Traceability and monitoring obligations under these licensing agreements especially regarding the use of licensed knowledge in foreign jurisdictions, does not depend entirely on the record system or the authorities appointed for the record administration. When establishing the National Commission for the Prevention of Bio Piracy by Law 28216 of 2004, Peru created a strategy to identify requested and granted patents on genetic resources use and collective knowledge of indigenous peoples.

The Commission strategy focused in endemic resources and related traditional knowledge. In 2005 Peru submitted a report to the IGC-WIPO CIG-OMPI identifying potential undue applications and patents regarding the following plant species: "*hercampuri*" (*Gentianella alborosea*), "*camu-camu*" (*Myrcia riadubia*), "*yacón*" (*Smallanthus sonchifolius*), "*caigua*" (*Cyclanthera pedata*), "*sacha inchi*" (*Plukenetia volubilis*), and "*chancapiedra*" (*Phyllanthus niruri*). On January 2013, Commission's actions identified 18 cases of bio piracy related to genetic resources of Peruvian origin and traditional knowledge of indigenous peoples, with 10 in favor of the Peruvian State (Valladolid Pers. com. 2013; Nemogá-Soto 2013b).

7.11 Perspective on Access and Benefit Sharing

The record system was established as a starting point to ensure benefit sharing on the use of collective knowledge. With an increased number of records, the perspective can be consolidated to the extent that it is profitable for domestic and foreign companies to pay royalties receiving legal access in exchange of a database on the uses of biodiversity technically referenced. In the government's view, companies using knowledge as the pharmaceutical industry must pay 10% of gross product sales related to collective knowledge to the Indigenous Peoples Development Fund provided by Law 27811 (The Republic 2011).

The government's view is not shared by industry's spokesman and advocates of a more conservative position on the nature of traditional knowledge and intellectual property rights. An example of this is the Peruvian Economy Institute (IPE), since it considers traditional knowledge as "a set of ancestral beliefs, some true and some false, based on the experience of native communities throughout many years" (IPE 2011). According to this, such knowledge for the IPE lack value in themselves because they are not generated by a scientific method, therefore, to collect royalties for their use discourages the performance of researches to validate them, concluding that "it makes no sense to pay royalties for the use of a non-limited public good" (IEP 2011).

7. Final Considerations

Conservation experiences guided by the understanding of interrelationships between biological and cultural diversity are relevant references especially when it comes to protection of traditional knowledge that are part of a comprehensive lifestyle of indigenous peoples and local communities that are in constant and dynamic interaction with nature. Ensuring the persistence of traditional knowledge and the lifestyle that supports them, should be the primary task for mega diverse countries and humanity as a whole, mainly given the contemporary environmental challenges and the increasing loss of biodiversity.

International legal instrument such as CBD, the ILO 169 Convention of 1989 and the UNDRIP, as well as the approach on conservation, bio cultural protection and the own vision of indigenous peoples and communities as Good Living together are references needed to develop a comprehensive protection system beyond the scope of commercialization of knowledge and intellectual property rights. WIPO's IGC is working on a protection instrument whose scope and international content should be considered in the creation of individual or group regimes in countries. National or regional initiatives such as the *sui generis* system developed by CAN up until now require an update with the approach of bio cultural diversity in order to articulate the indigenous worldviews on protection systems; through their participation it is up to indigenous peoples to decide over the protection instruments and the development of alternatives based on the use of their traditional knowledge exercising their right to self-determination recognized worldwide.

Some forms of intellectual property can ensure compliance of obligations in the benefit sharing derived from the use of traditional knowledge and biological resources. Thus, designations of origin, geographical indications, certificates of origin and records of collective knowledge among others, could be used by communities that choose to market their knowledge and their by-products. In this regard, the design of protection alternatives of traditional knowledge and the rights of their holders under intellectual property are instrumental and can be used to protect them in local communities and indigenous peoples and in their trade relations with outer societies.

Record of collective knowledge for example can contribute to establishing a trading platform with greater assurance for communities who choose to license their collective knowledge; however, its feasibility require communities to articulate themselves as suppliers in a market of indigenous knowledge on biodiversity, and that users identify the record system as an institutional channel to legally access them at low transaction costs. PIC and MAT can be collected in a licensing accepted by the record to ensure legal certainty required by different actors. Thus, record of collective knowledge would operate as an extension of the intellectual property system so that their original holders receive a fair compensation for their use.

In this scenario, the record system serves its purpose if it ensures the conduction of business transactions on collective knowledge, it works as a mechanism to collect royalties for the use of knowledge, contributes to the patenting of inventions related to indigenous knowledge with industrial and commercial applications, and prevents the granting and undue exploitation of intellectual property rights. However, if the conditions of the communities are of economic poverty and lack of basic services such as health and drinking water, with no political organization and representation, a record system of knowledge outside the community control can become just another mechanism rather limited to extract information or defensive protection.

Protection systems require focusing the comprehensiveness of traditional knowledge of not just those related to biodiversity as in the case of the Peruvian record system. Despite this limitation, the Peruvian system is both a pioneer experience in the region and a reference to evaluate the complex processes of development and implementation of a protection system. As such, the record system meets part of its objectives to help prevent misappropriation of traditional knowledge and resources from Peru; however, its effect would be lower without the complementary activities from the National Commission against Bio Piracy.

The initial defensive approach of this Commission, progressively more oriented to implement the regulations on access and benefit sharing, opens a new possibility of institutional arrangements with positive results for the country and indigenous peoples but also for bio prospecting companies and researchers. The above perspective may be possible bearing in mind that the protection system of traditional knowledge is not limited to establishing a regulation. Their own views on economic, social and cultural development of indigenous peoples are always needed when defining the objectives and the designing of protection systems of traditional knowledge through their representative organizations. Therefore, preservation of traditional knowledge and lifestyles that enable their permanent regeneration require actions that go beyond the intellectual property system.

The experiences of cultural reaffirmation guided by the understanding of the interrelationships between human groups and nature, as well as practices of the concept of bio cultural collective knowledge show that this approach has the potential to guide the research on biodiversity conservation, the protection action and the defense of the rights of indigenous peoples and communities. The challenge to work for the conservation of bio cultural diversity and for the rights of indigenous peoples on their lands and natural resources at the same time is to find innovative ways to support the right to self-determination of indigenous peoples (Davidson-Hunt *et al.* 2012). The preservation of knowledge, innovations and practices related to bio cultural diversity is urgent and needed for indigenous peoples but also for humanity.

Conservation of bio cultural diversity requires capacity building and living conditions of indigenous peoples and communities. The use of records locally under the control and administration of indigenous and local authorities can give relevance to the cultural, social and political contexts of the corresponding people, with broader and more comprehensive goals.

In this case, records and databases will have a different configuration in order to share traditional knowledge, conserve and preserve them for future generations. At the same time, cultural, spiritual or religious content as well as beliefs related to the use of collective knowledge will acquire greater relevance in this scenario, compared with the barely marginal interest that they have today for those who have access in order to develop products. In practice, these public and confidential record systems as the one established in Peru do not emphasize on cultural and spiritual elements.

The situation would be different if the objective was to preserve the traditions, uses and lifestyles of indigenous peoples exercising self-determination since the cultural, social and political contexts of the people or community would be essential to design and adopt relevant strategies. Aside from that, the use of indigenous names on biological species in the record of collective knowledge for example, becomes a technical detail that contributes to identify biological resources and to strengthen the information system, but it is irrelevant for the understanding of sacred, religious or spiritual meanings and stories related to them.

Ultimately, local record systems controlled by communities could use technological tools as databases to store digitally ancestral practices that nourish the free exchange of seeds, knowledge and information. Thus, these practices of reciprocity and mutual aid take place in areas with high biodiversity, correlating with distinct features and processes of ancestral cultural identities when persisting for example in the exchange of knowledge and seeds among agro bio diverse communities (Lapeña 2012). The strengthening of solidarity patterns help to minimize the potential conflicts over ownership, royalties and exclusive rights among communities especially since the main goal in this case is to contribute to common property of knowledge, practices and mutual benefits.

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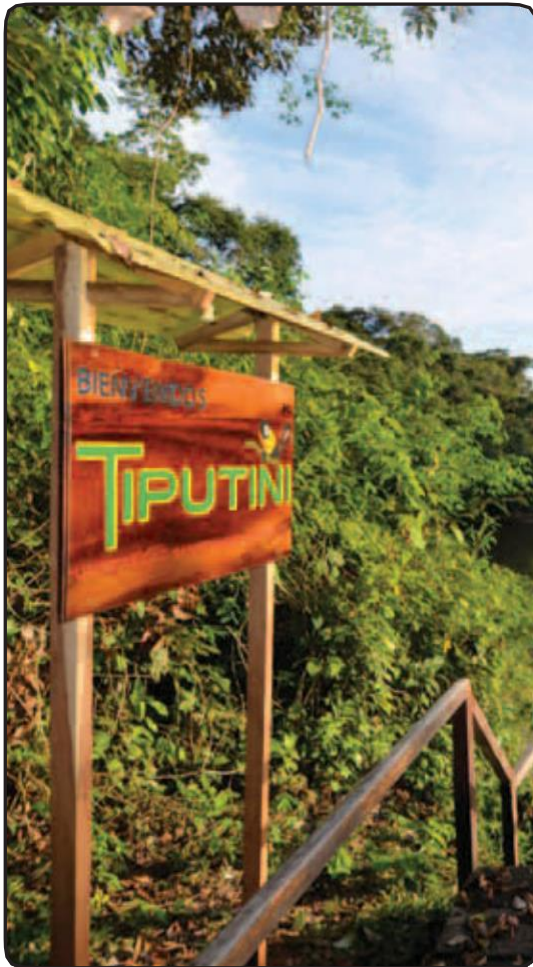
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Acceso a recursos genéticos en América Latina y el Caribe:
retos para la distribución justa y equitativa en los beneficios



Diana Herrera y Montserrat Rios



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

In Latin America and the Caribbean access to genetic resources and their protection stems from the need for fair and equitable benefit-sharing between suppliers and users. In this situation, it is essential to include an analysis of which tools may improve the capabilities in the region, exchanging experiences among the eight countries of the Regional Project IUCN-UNEP/GEF- ABS-LAC, as well as practices to adopt the Nagoya Protocol and ratify it in terms of national sovereignty through the legislation of each country.

The objective behind the promotion of scientific research and its relation to ABS, the commercialization of genetic resources and the indigenous worldview about biodiversity, considering actual experiences in the region, is to strengthen the implementation of schemes for Access to Genetic Resources and Benefit Sharing (ABS), while analyzing a number of critical issues in the countries involved. As such, it would be a priority that legal developments in standards, regulations and legislation related to national ABS overcome national complexities and difficulties. In this way, an alignment could be established with the objectives of the CBD in megadiverse countries and the real benefits that genetic resources generate could be positioned.

In this sensitive national and international legal context, it becomes necessary to translate the experiences of each country into regional challenges for the implementation mechanisms in the future. Indeed, time will be a catalyst that will provide a response regarding how one day the correct articulation of the multiplicity of actors of the interplay between research, marketing and the indigenous worldview with biodiversity, might make it possible to achieve an appropriate implementation of ABS in the region. Thus, it is suggested to consider the following thoughts as a contribution to move forward:

- i. Research on biological and genetic diversity which are developed in countries of origin have more difficulties than those executed abroad, because national researchers need more public and private scientific-technological support to develop advanced experiments so they can avoid sending samples abroad, for instance, for molecular analysis of genetic material.
- ii. Studies of schemes that disseminate genetic data on the basis of open and free criteria show that some biopiracy situations cannot be prevented because making the information available by including it in the technical status does not prevent the possibility of obtaining patents. Likewise, facilitating public access can be tricky, because those who gain access to certain information might apply for patents to modify it, transform it or combine it.

Herrera, D. and Rios, M. 2013. Access to genetic resources in Latin America and the Caribbean: Challenges for fair Benefit-Sharing. In: Rios, M. and Mora, A. (Eds.), Access to Genetic Resources in Latin America and the Caribbean: Research, Commercialization and Indigenous worldview. IUCN-UNEP/GEF-ABS-LAC. Quito, Ecuador. Pp. 113-116.

- iii. Potential economic relevance on the use of genetic resources and traditional knowledge, because the lack of studies that provide information on what opportunities exist and the necessary conditions to exploit them, needs to be overcome. Countries such as Costa Rica and Cuba show research and development initiatives through international alliances because they have national regulations, strengthened laboratories and technical experiences which are a reference to implement projects in their territory, that apply on their behalf.
- iv. Experiences that show how essential it is to integrate worldviews of indigenous peoples in the protection systems of traditional knowledge, since they are the result and the means by which their owners achieve their survival in their environment. Therefore, we must ensure the preservation of indigenous knowledge and safeguard it from unauthorized access.
Currently, it is still difficult to establish regulations and protective systems with respect to traditional knowledge. Thus, countries like Peru seek to design sui generis protection models that incorporate the indigenous worldview complemented by record systems for collective knowledge and contributions of the National Commission against Biopiracy. Peru's strategy is an incentive to conserve and value traditional knowledge, and it is a reference for other countries. It also recognizes customary law, community protocols and prior informed consent, providing legal security to all stakeholders.
- v. Everyday practices that demonstrate the theory must be applied to access regimes in Latin America and the Caribbean, identifying the indicators that signal a shift in the direction of research to accompany regulations or modifications that take into account the changing dynamics of science. At the same time, the participation in a fair and equitable benefit sharing for products derived from genetic resources is ensured.
- vi. The analysis of case studies in countries of the region show that when ratifying the Nagoya Protocol, a commitment is made to create conditions that promote national research and to determine when it is commercial or noncommercial. This fact means recognizing that a non-commercial intent may change over the course of the research when there are findings with market potential; so, access regimes should prevent a swap which may be adopted in these procedures and allows the researcher or interested party to carry on.
- vii. Legal instruments in the region must be aligned in countries which are Parties through national legislation, because once the Nagoya Protocol is ratified, regulations will apply for access to genetic resources. The purpose of this would be to achieve synergy between constitutional tools, and workshops and seminars between the focal points of the various treaties are recommended to improve information and define their areas of operation. The big challenge for Latin America and the Caribbean will be to generate opportunities nationwide. In order to do this, it is essential to review administrative, legal and political measures and harness the benefits of the use of genetic resources and their byproducts. At present, most national laws comply with access standards, but it is still necessary to define clearer attributions and procedures.



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



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