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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Published by: UICN, Quito, Ecuador.

Quotation: Rios, M. and Mora, A. (Eds.). 2014. Access to Genetic Resources in Latin America and the Caribbean: Research, Commercialization and Indigenous worldview. IUCN-UNEP/GEF-ABS-LAC. Quito, Ecuador. 116 pp.

Quotation for Case Study: Nemogá-Soto G.R.; D. A. Rojas Díaz y O. A. Lizarazo Cortes. 2014. Biodiversity research in megadiverse countries: strategies for scientific and technical alliances. In: Rios, M. and Mora, A. (Eds.). 2014. 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.

Cover Illustration: Roger Ycaza

Graphic Design: Montserrat

Rios

Catalina León, Manthra, comprehensive communication and publishing, Quito, Ecuador.

Produced by: IUCN's Regional Office for South America.

Printed by: Manthra (www.manthra.net), Quito, Ecuador.

Available at: IUCN's Regional Office for South America
Calle Quiteño Libre E15-12 y la Cumbre
Quito – Ecuador
www.iucn.org/sur // www.adb.portalces.org

First Edition: Quito, February 21, 2014 (300 copies).
The paper used for printing is "environment-friendly", comes from managed forests and has the following features: it is alkaline (ensures its durability over time), it has post-consumer recycled content, and it contains FSC certified fibers and fibers bleached without the use of chlorine. It also complies with the following certifications: Elemental Chlorine Free (ECF); Forest Stewardship Council (FSC); Green seal, Laser & Ink Jet Guaranteed; Teach Ready 50/30, 50% & 30% recycled post-consumer and Green seal E (product manufactured with water, wind or solar energy).

ISBN: 978-9978-9932-4-8

National Copyright Registry: Nº 043137

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).

Cataloging of the Publication

333.95 U581

International Union for Conservation of Nature. (IUCN)

Access to Genetic Resources in Latin America and the Caribbean: Research, Commercialization and Indigenous worldview / Montserrat Rios and Arturo Mora, Editors – 1st Edition. -- Quito: IUCN, 2014.

116 p.: il.; 25 cm.

ISBN 978-9978-9932-4-8.

Published in support of the implementation framework for the Nagoya Protocol on Access to Genetic Resources and Fair Benefit-Sharing from their Utilization.

Contents: 1. Biodiversity research in megadiverse countries: strategies for scientific and technical alliances. 2. Commercialization of biodiversity: markets for genetic resources and biochemical products. 3. Interrelationship between indigenous worldview and biodiversity: How to protect traditional knowledge and genetic resources? 4. Access to genetic resources in Latin America and the Caribbean: Challenges for fair Benefit-Sharing.

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

Commercialization of biodiversity: markets for genetic resources and biochemical products

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

Gabriel Ricardo Nemogá-Soto and Jorge Cabrera Medaglia

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 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.

Nemogá-Soto G.R. and J. Cabrera Medaglia. 2014. Commercialization of biodiversity: markets for genetic resources and biochemical products. In: M. Rios and A. Mora (Eds.), Access to Genetic Resources in Latin America and the Caribbean: Research, Commercialization and Indigenous worldview. IUCN-UNEP/GEF-ABS-LAC. Quito, Ecuador. Pp. 43-78.

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).

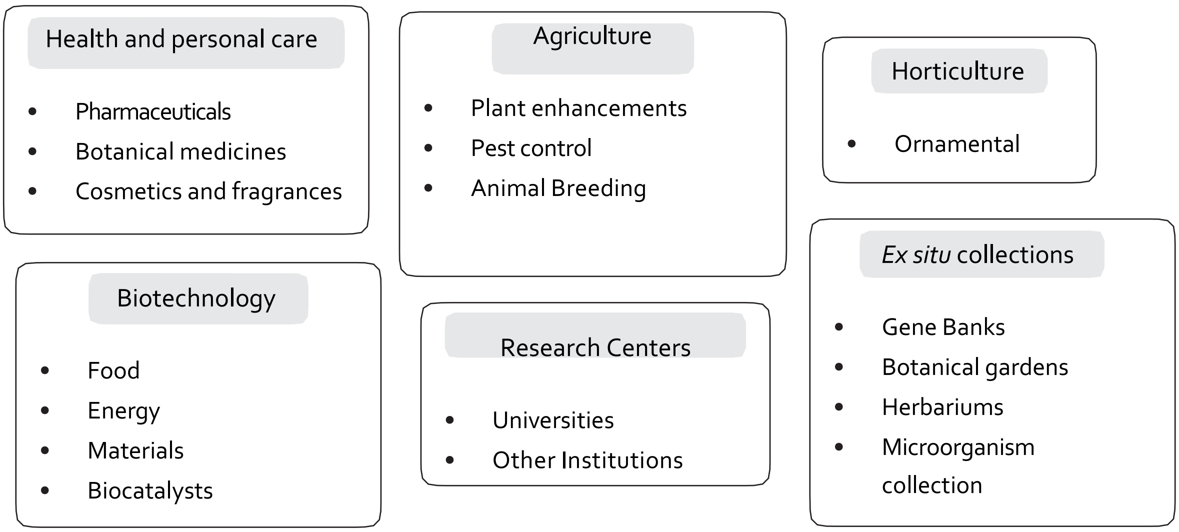

Figure 1. Potential areas for the use of genetic resources and associated traditional knowledge. Source: Holm-Müller, Richerzhagen and Täuber 2005.

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 billon	A high percentage comes from genetic resources, for instance, 47% of medicines for cancer in the period of 1981-2006
Biotechnology	US$ 70 billon	Many byproducts coming from genetic resources, such as microorganisms and enzymes, among others
Crop Protection	US$ 30 billon	Some byproducts from the use of genetic resources
Seeds	US$ 30 billon	All byproducts from the use of genetic resources
Ornamental Horticulture	Amount of global imports US$ 14 billon	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 biopharmaceutics, 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) USD $ 833 (food enzymes)
Products for agriculture and forestry	Transgenic seed	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 (GIIB) 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	*Lonchocarpus felipei**	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
Diversa (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
Follajes Ticos	Palmas	Ornamental improvement	2000-2004
La Gavilana S.A.	Microorganisms	Agriculture	2000 – to present
Laboratorios Lisan S.A.	Plants	Human health and phytomedicines	2000-2004
Bouganvillea S.A.	*Quassia amara*	Agriculture	2000-2004
Agrobiot S.A.	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			
Industrias El Caraíto S.A.	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
Laboratorios Vaco S.A.	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 *Aedes aegypti*	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
Florex of Costa Rica	Microorganisms and plants	Cleaning products	2010 - to present
Pharma Mar	Marine organisms	Human health	2012 - to present

Source: Cabrera Medaglia 2013.
* Organisms that produce DMDP (2R,5R-Dihidroximetil-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 (*"ají"*, *"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) (GIIB 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 IIAP 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 (IIAP 2009). The understanding of the complexity of the topic and the participation of multiple stakeholders for the IIAP 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 (IIAP 2009).

Approaches to the development of technology-intensive products require a comprehensive view such as the one proposed by the IIAP, 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 "(IIAP 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 *"ají"*, 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 Export Volume (kg) Botanical Ingredients	2008 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 Aleixandra 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 that 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 and 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 (GIIB 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 where 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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