Six Case Studies in Latin America and the Caribbean: Access to Genetic Resources and Benefit Sharing

IUCN's Regional Office for South America

PNUMA

fmam FONDO PARA EL MEDIO AMBIENTE MUNDIAL
INVERTIMOS EN NUESTRO PLANETA

Published by: IUCN, Quito, Ecuador.

Quotation: Rios, M. and Mora, A. (Eds.). 2013. **Six Case Studies in Latin America and the Caribbean: Access to Genetic Resources and Benefit Sharing**. IUCN-UNEP/GEF-ABS-LAC. Quito, Ecuador. 120 pp.

Quotation for Case Study: Cabrera Medaglia, J. 2013. The venom of the "red scorpion" and other products derived from plant diversity. In: Rios, M. and A. Mora (Eds.). 2013. **Six Case Studies in Latin America and the Caribbean: Access to Genetic Resources and Benefit Sharing.** IUCN-UNEP/GEF-ABS-LAC. Quito, Ecuador. Pp. 65-75.

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, December 12, 2013 (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: 978-9978-9932-3-1

National Copyright Registry: Nº 042766
Translation into English: FIDELIS (March 18 2014)

Six Case Studies in Latin America and the Caribbean: Access to Genetic Resources and Benefit Sharing.

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

Montserrat Ríos 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).

Contents

Abbreviations and Acronyms 7

Foreword (Spanish)
Mr. Bakary Kante, Dr. Braulio Ferreira de Souza Dias, Dr. Naoko Ishii and Mrs. Julia Marton-Lefèvre 9

Foreword
Mr. Bakary Kante, Dr. Braulio Ferreira de Souza Dias, Dr. Naoko Ishii and Mrs. Julia Marton-Lefèvre 10

Acknowledgements
Arturo Mora 11

Authors 12

Introduction
Arturo Mora 13

Case Study in Colombia:
Research on a microorganism of the genus *Lactococcus sp.*
Institute of Biotechnology, National University of Colombia
Gabriel Ricardo Nemogá-Soto and Dalí Aleixandra Rojas Díaz 15

1. Introduction 17
2. Contractual agreements 18
    - 2.1 Obligations and permits for scientific research 18
    - 2.2 Obligations of the access contract for a by-product with industrial application purposes 18
3. Project and research activities description 19
    - 3.1 Collection activity 19
    - 3.2 Access to genetic resources 19
4. Detail of benefits included in the agreements 20
    - 4.1 Non-monetary benefits 20
    - 4.2 Monetary benefits associated to industrial property 20
    - 4.3 Monetary benefits associated with the commercial exploitation 20
    - 4.4 Benefits generated and shared to date 20
5. Scope and status of project activities 21
    - 5.1 Research status 21
    - 5.2 Traceability and monitoring mechanisms 21
    - 5.3 Impact on local socio-economic and / or institutional conditions 21
    - 5.4 Information regarding the request for Intellectual Property Rights and its status 22
    - 5.5 Description of conflicts or agreements reached 22
6. Lessons learned 22
7. Bibliography 23
8. Websites 23
9. Interviews 23

Case Study in Costa Rica:
Access to genetic resources, fair benefit sharing of and legal analysis of the agreement between the National Biodiversity Institute of Costa Rica, the Harvard University and the University of Michigan

Jorge Cabrera Medaglia 25
1. Introduction 27
2. National Biodiversity Institute of Costa Rica: Overview and the Bioprospecting Strategic Action Unit 27
2.1 Strategic Action Units 28
2.2 Institutional activities and alliances 28
3. Development of negotiations and strengthening of the Bioprospecting Strategic Action Unit 29
3.1 Chemical prospecting of biodiversity 30
3.2 Biotechnological prospecting of biodiversity 30
3.3 Biodiversity Sample Collection and Management 31
3.4 INBio Databases 31
4. INBio Sponsorship for the "International Cooperative Biodiversity Group": bioprospecting applied to human health 34
4.1 Biological wealth and diversity of ecosystems Costa Rica 35
4.2 Biological resources used as source of new compounds 35
4.3 Experience and knowledge of INBio 36
5. Access and research activities 36
5.1 Associated Programme 1 (AP1) 36
5.2 Associated Programme 2 (AP2) 37
5.3 Associated Programme 3 (AP3) 37
5.4 Associated Programme 4 (AP4) 39
5.5 Collection activities 39
6. National legislation acosta Rica and legal framework for ABS 40
6.1 Legislation related to the Biodiversity Act and Rules for Access 40
6.2 Scope of application for ABS 40
6.3 Procedure for access to genetic resources 42
6.4 Basic requirements for access to genetic resources 42
6.5 The case of *ex situ* collection 45
7. Tracking and monitoring mechanisms used by the Technical Office 47
8. Compliance with legal requirements for the implementation of activities of the "International Cooperative Biodiversity Group" 48
8.1 Materials collection 49
8.2 Registration of the interested party 49
8.3 Presentation of the permit request and technical guide 50
9. Negotiation of prior informed consent 51
10. Conditions of the permit granted to access genetic resources at the National Biodiversity Institute of Costa Rica 54
10.1 Scope of the collection permit granted at INBio 55
11. Contractual agreements and fair benefit sharing 56
11.1 Contractual negotiation between the scientific consortium and the business associates 58
12. Monitoring arrangements 58
12.1 Legal tracking and monitoring mechanisms used by INBio 60
13. Benefits, project results and intellectual property 61
14. Lessons learned 61
15. Websites 63

Case Study in Cuba:
The venom of the "red scorpion" and
other products derived from plant diversity
Jorge Cabrera Medaglia *65*
1. Introduction 67
2. Biological resources and their by-products 67
2.1 Vimang 68
2.2 Venom of the "red scorpion" 68
2.3 Phytoestrogen X 69
2.4 Actual or potential use of three by-products of biological resources 69
3. Main national and foreign stakeholders 70
4. Contractual agreements for the development of by-products 71
5. Description of the activities of research and collection 72
5.1 Venom of the "red scorpion" 72
5.2 Mango Tree bark 72
5.3 Phytoestrogen from the leaves of beach *salvia* 72
6. Benefits generated and shared to date 72
7. Scope and status of research activities 73
7.1 Mechanisms of traceability and monitoring 73
7.2 Impact on local socio-economic and / or institutional conditions 73
7.3 Intellectual property rights status 73
7.4 Description of conflicts or agreements reached 74
8. Lessons learned 74

Case Study in Ecuador:
Global Ocean Sampling Expedition, Galapagos National Park:
collection activities and implementation of legislation
Gabriel Ricardo Nemogá-Soto y Oscar Andrés Lizarazo 77
1. Introduction 79
2. Biological resources and by-products of the
"Global Ocean Sampling Expedition", Galapagos National Park 79
2.1 Actual or potential use of biological resources 80
2.2 Main national and foreign stakeholders 80
3. International contractual agreements and national stakeholders 80
3.1 Detail of benefits included in the agreements 81
4. Results of the "Global Ocean Sampling Expedition",
Galapagos National Park 81
4.1 Benefits generated and shared up until 2012 81
4.2 Scope and status of activities 82
4.3 Chronology of the expedition led by J. Craig Venter 82
5. Models for the dissemination of results 83
6. Lessons learned 84
7. Bibliography 87
8. Websites 88

Case Study in Panama:
"International Cooperative Biodiversity Group"
Jorge Cabrera Medaglia 89
1. Introduction 91
2. Operating Models of the "International Cooperative Biodiversity Group" 91
2.1 General rules for projects of the "International Cooperative Biodiversity Group" 92
3. The "International Cooperative Biodiversity Group" and Panama: collaborating on research of biodiversity and its by-products 93
3.1 Actual or potential use of genetic resources in by-products 94
4. Legislation applicable to the access to genetic resources in Panama 94
5. Participants of the project conducted in Panama by the "International Cooperative Biodiversity Group" 96
5.1 Project activities and programs at a national and international level 96
5.2 Contractual agreements among collaborators and legal implications 97
6. Benefit sharing in Panama and the development of the project 100
6.1 Impact of the project at a local socio-economic and / or institutional level 101
7. Intellectual property rights and patents 102
8. Lessons learned 102
9. Bibliography 103
10. Websites 103
11. Interviews 103

Case Study in Peru:
Registry of collective knowledge associated with biodiversity
Gabriel Ricardo Nemogá-Soto 105
1. Introduction 107
2. Potential use of genetic resources and its by-products 107
3. Actual and potential use of collective knowledge 108
4. Bioprospecting Project actors 108
5. Legal instruments and fair benefit sharing 109
6. Project description 109
6.1 Activities for the registry of collective knowledge 110
7. Legislation and fair benefit sharing 110
8. Research, follow up and monitoring activities 111
9. Impact of the registry system for collective knowledge on local socio-economic and / or institutional conditions 113
10. National Anti-Biopiracy Commission: Intellectual property rights and status of patents 113
11. Lessons learned 114
12. Bibliography 116
13. Websites 116

ABS in Latin America and the Caribbean:
challenges to implementation mechanisms
Diana Herrera y Montserrat Rios 117

Abbreviations and Acronyms

(* Acronym has been kept in original Spanish form)

ABS	Access and Benefit Sharing of genetic resources
ACAHN	*Arenal Huetar Norte* Conservation Area*
ACAT	*Arenal Tempisque* Conservation Area*
ACCVC	*Cordillera Volcánica Central* Conservation Area*
ACG	*Guanacaste* Conservation Area*
ACLAP	*La Amistad Caribe* Conservation Area*
ACOSA	*Osa* Conservation Area*
ACT	*Tempisque* Conservation Area*
ACTo	*Tortuguero* Conservation Area*
ANAM	National Environmental Authority*
ANLA	National Environmental Licensing Authority*
AP	Associated Programme
CAN	Andean Community of Nations*
CAR	Regional Autonomous Corporation of Cundinamarca *
CBD	Convention on Biological Diversity
CDA	Confidentiality Disclosure Agreement
CIDEM	Drug Research and Development Center*
CIG	Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore*
CIMAR	Centre for Research in Marine Sciences and Limnology of the University of Costa Rica*
NB	National Commission against Biopiracy*
CONAGEBIO	National Commission for Biodiversity Management *
CONAM	National Environmental Council*
CONAP	Confederation of Amazonian Nationalities of Peru *
CQF	Center of Pharmaceutical Chemistry *
CRIRAPAQ	Indigenous Nationalities Council and Center of Indigenous Cultures of Peru*
CTPI	Traditional Knowledge of Indigenous Peoples*
EPO	European Patent Office
FDPI	Indigenous Peoples Development Fund
GEF	Global Environment Fund
HTS	High-throughput screening
IBEA	Institute for Biological Energy Alternatives
ICBG	International Cooperative Biodiversity Group
IES	Institute of Ecology and Systematic*
IIAP	Peruvian Amazon Research Institute*
INA	National Support Institution*

INBio	National Biodiversity Institute of Costa Rica*
INDECOPI	National Institute for the Defense of Competition and the Protection Intellectual Property*
INDICASAT	Institute of Advanced Scientific Research and High Technology
INIA	National Agricultural Research Institute
INRENA	National Natural Resources Institute*
INRENARE	National Non-Renewable Natural Resources Institute*
IPR	Intellectual Property Rights
IUCN	International Union for Conservation of Nature
JPO	Japan Patent Office
KRIB	Korean Research Institute of Bioscience and Biotechnology
LABIOFAM	Entrepreneurial Group of Biopharmaceutical and Chemical
LAC	Latin America and the Caribbean
MADS	Ministry of Environment and Sustainable Development*
MAE	Ministry of Environment of Ecuador*
MAT	Mutually agreed terms
MINAE	Ministry of Environment and Energy*
MMV	Medicine for Malaria Venture
MTA	Material transfer agreement
MU	Memorandum of understanding
NCDDG	National Cooperative Drugs Discovery Group
NIH	National Institute of Health
NSF	National Science Foundation
PEFI	Permit for scientific research*
PIC	Prior Informed Consent
PNN	National Natural Parks of Colombia*
RMIB-LAC	Indigenous Women's Network on Biodiversity of Latin America and the Caribbean
SAU	Strategic action unit
SCNA	Swiss Academy of Sciences
SEDEFA	Ecuadorian Society of Forest and Environmental Law*
SETENA	National Technical Secretariat*
SINA	National System of Conservation Areas*
SPD	Peruvian Society for Environmental Law*
STR	Smithsonian Tropical Research Institute
TO	Technical Office
UNC	National University of Colombia*
UNEP	United Nations Environment Programme
USPTO	United States Patent and Trademark Office
WIPO	World Intellectual Property 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 de 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 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 diseminación 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.

Sr. Bakary Kante
de

Director
División de Legislación
y
Convenciones
Ambientales
PNUMA

Dr. Braulio Ferreira
Souza Dias

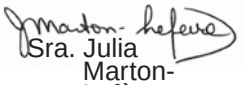
Secretario
Ejecutivo

CDB

Dra. Naoko Ishii

Directora Ejecutiva
y
Presidenta

GEF



Sra. Julia
Marton-
Lefèvre

Directora
General

UICN

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, private sector, etc.). 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 Target 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.

Mr. Bakary Kante de	Dr. Braulio Ferreira Souza Dias	Dr. Naoko Ishii	Sra. Julia Marton-Lefèvre
Director Division of Enviromental Law and Conventions UNEP	Executive Secretary CBD	CEO and Chairperson GEF	General Director UICN

Acknowledgements

The Coordination of the Project “Strengthening the Implementation of Access and Benefit Sharing Regimes in Latin America and the Caribbean IUCN-UNEP/GEF-AB-LAC” would like to thank the following people and institutions for their collaboration and participation in this process:

To the National Focal Points, who led the respective processes in eight countries and also shared their experiences working on the issue of ABS at a regional level. Their continuing participation contributed to achieving the project objectives.

To the members of the various State institutions, who deserve special recognition and are represented by: Beatriz Acevedo and Javier Camargo (Ministry of Environment and Sustainable Development of Colombia); Marta Liliana Jiménez (Ministry of Environment and Energy of Costa Rica); Mayra Fernández and Daysi Vilamajó (Ministry of Science. Technology and Environment of Cuba); Wilson Rojas, Cristina Quiroga and Verónica Lemache (Ministry of Environment of Ecuador); Indarjit Ramdass, Diana Fernandes, Damian Fernandes and Stacy Lord (Environmental Protection Agency Guyana); Darío Luque and Israel Tejada (National Environmental Authority of Panama); Dora Velásquez and Emma Rivas (Ministry of Environment of Peru); and Marina Hernández and Mercedes Peguero (Ministry of Environment and natural Resources of the Dominican Republic).

To the various institutions that gave their support through technical collaboration and strategic alliances during the process, represented by: Alejandro Lago and Luciana Silvestri (UNESCO Professorship of Territory and Environment of the University Rey Juan Carlos); Florina López and Yolanda Terán (Indigenous Women's Network on Biodiversity of Latin America and the Caribbean (RMIB-LAC); Begoña Venero (WIPO); Grethel Aguilar, Víctor Inchausty, Sonia Peña and Thomas Greiber (IUCN); María Cristina Puente and Carla Cárdenas (Ecuadorian Society of Forest and Environmental Law, SEDEFA); María Julia Oliva (UEBT); Lilián Carrera and Fernando Nogales (Ecuadorian Institute of Intellectual Property, IEPI); Andrés Valladolid (National Anti-Biopiracy Commission of Peru); Johanna von Braun (Natural Justice); Manuel Ruiz (Peruvian Society for Environmental Law, SPDA); Karine Payet-Lebourges (DIVERSITAS), and Susette Biber-Klemm (Swiss Academy of Sciences, SCNAT).

To the main researchers and collaborators of the project, represented by: Jorge Cabrera Medaglia, Gabriel Ricardo Nemogá-Soto, Montserrat Rios and Diana Herrera.

To the Project’s Steering Committee, represented by: Kristin McLaughlin (UNEP-GEF); Kamar Yousuf (UNEP-HQ); Andrea Brusco and Alex Pires (UNEP-ROLAC); Valerie Normand and Beatriz Gómez (SCBD); Tea García (IUCN-ORMA), y Aracely Pazmiño (IUCN-South).

Arturo Mora,
M.A.
Regional Project Coordinator IUCN-UNEP/GEF ABS LAC

Authors

Jorge Cabrera Medaglia
Institution: Legal Adviser, National Biodiversity Institute of Costa Rica
Professor, Universidad de Costa Rica
Address: Apartado 317-3015, San Rafael de Heredia
Costa Rica
E-mail: jorgecmedaglia@hotmail.com jcabrera@cisdl.org

Oscar Andrés Lizarazo Cortés
Institution: National University of Colombia
Address: Edificio 201, Ciudad Universitaria
Bogotá, Colombia
E-mail: oalizarazoc@unal.edu.co
oscarlizarazo@gmail.com

Gabriel Ricardo Nemogá-Soto
Institution: Associate Professor, University of Winnipeg,
Canada Researcher, Research Group, PLEBIO
National University of Colombia
Address: 515 Portage Avenue, Winnipeg, Manitoba
Canada R3B 2E9
E-mail: grnemogas@gmail.com
g.nemoga@uwinnipeg.ca

Dalí Aleixandra Rojas Díaz
Institution: Research Group, PLEBIO
National University of Colombia
Address: Calle 130b Nº 7ª-75
Bogotá, Colombia
E-mail: darojasd@gmail.com

Introduction

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 this first publication aimed at improving the knowledge of different actors and stakeholders in the region with regards to this topic.

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 of the regional result has made it possible to present six national case studies in this publication, which is related to lessons learned in the areas of: the negotiation of genetic resources, and the drawing up of contracts for ABS or related benefits, among others. The publication compiles valuable experiences, systematized and discussed by the work teams of doctors Jorge Cabrera from Costa Rica and Gabriel Nemogá from Colombia. Both are international experts who collaborate with the Project and interact with national focal points improving the capacity process.

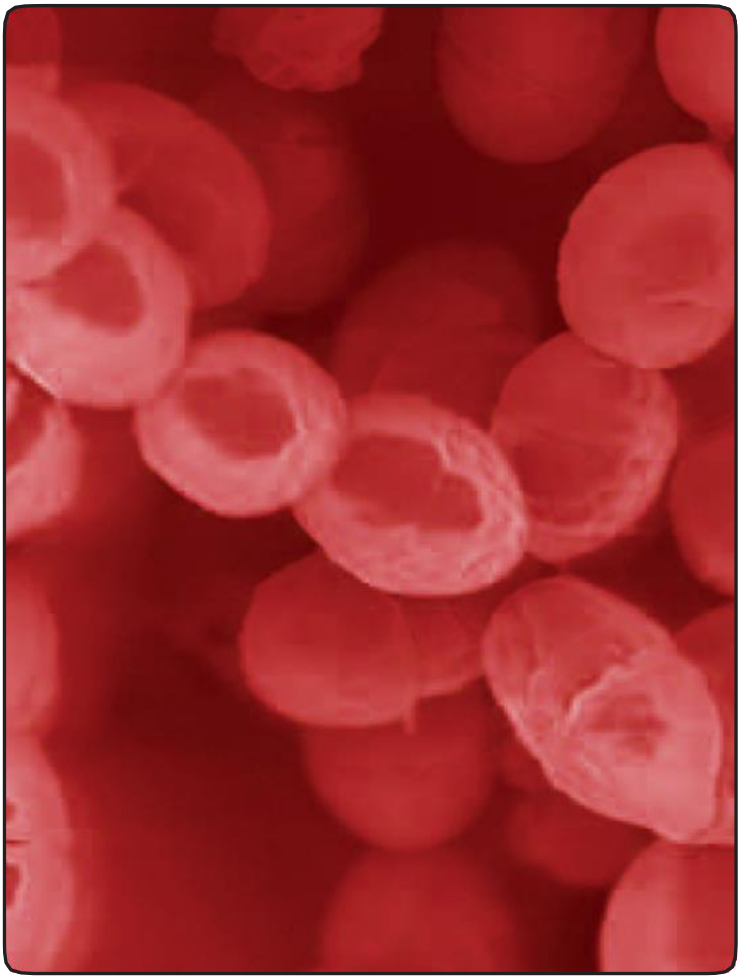
The chapters in this document explain how the countries of the region clearly recognize their wealth in genetic diversity, but face the enormous challenge of regulation the access to these biological resources, as well as defining and sharing the benefits (be they monetary or not) that all that biological wealth may yield. In this respect, all six case studies will reveal the close links among the various segments of society related to the issue of ABS, represented by: local communities and indigenous peoples; researchers working on bioprospecting and scientific research; the private sector, and universities, among the main groups.

There is a space of significance in the coordination of ABS actions among the different State authorities and institutions of each country, including the ministries related to environment, development, health and trade, as well as intellectual property institutions. Success in an effective articulation of all these instances, would translate into the establishment of ABS National Systems in each country, which in turn would set an example to foster the interest on the issue from various social sectors in Latin America and the Caribbean.

Ultimately and with regards to this particular body of work, I would like to express my gratitude to all the colleagues who contributed to it with their scientific and technical assistance, as well as with their recommendations for the final manuscript: to Leonardo Auz, Engr. (Ministry of Environment of Ecuador) for the geographical illustration of the map of Latin America and the Caribbean; to Dr. Jorge Celi, Ph.D (Research Coordinator at Freshwater Biogeochemistry Laboratory, Michigan State University) for his collaboration with scientific papers related to some of the case studies, and to Dr. Nora Martín, Ph.D (Administrative Coordinator of the Strategic Action Unit on Bioprospecting, in the National Biodiversity Institute of Costa Rica). Also, for contributing with photographic archives, I would like to thank: Luis de Armas Chaviano (IES), Joseph Heintz and Kenneth Todar (University of Wisconsin, Madison); Fabio Hidalgo (INBio); Kevin Tidgewell; and Manthra, comprehensive communication and publishing, for donating several photographs related to indigenous peoples from Peru and wildlife from the Galapagos Islands in Ecuador.

Arturo Mora, M.A.
Regional Project Coordinator IUCN-UNEP/GEF ABS LAC

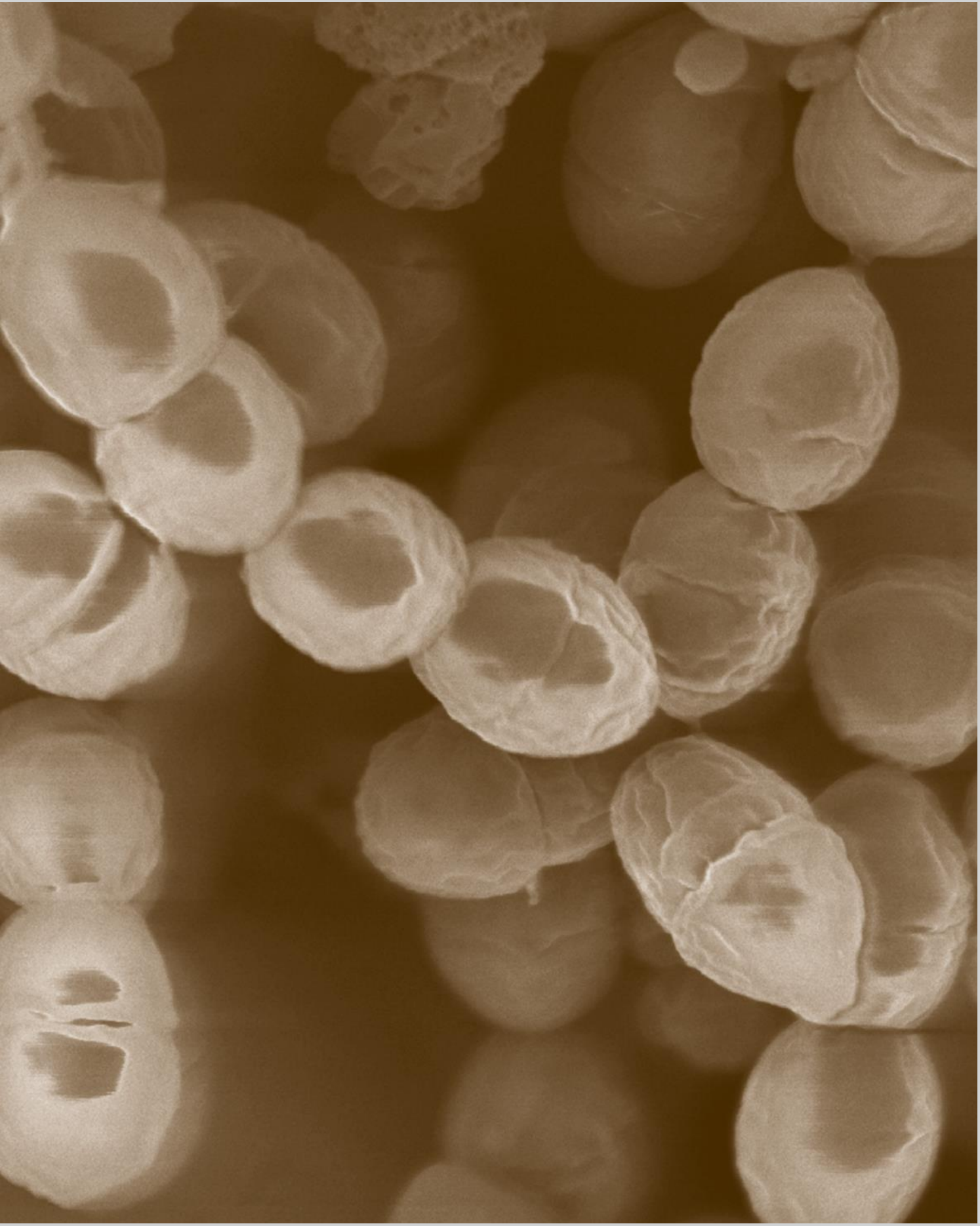
Case Study in Colombia



© *Lactococcus lactis,* Joseph Heintz and Kenneth Todar - University of Wisconsin

Gabriel Ricardo Nemogá-Soto and

Dalí Aleixandra Rojas Díaz



Research on a microorganism of the genus *Lactococcus* sp., Institute of Biotechnology, National University of Colombia

1. Introduction

Ever since the Convention on Biological Diversity (CBD) entered into force in 1993, the paradigm of open access to biodiversity under the concept of common heritage of mankind has changed with the application of a proprietary approach that redefines the right of countries over genetic diversity. Thus, the trend towards the establishment of intellectual property rights through patents and plant breeders' rights –beginning in the 1920s in the United States and in the 1950s in Europe– is assumed.

In 1992, the sovereignty of countries over their own biodiversity is recognized, establishing the commitment to facilitate the access to genetic resources (Art. 15, CBD). And so it is that in 1996, the states of the Andean Community of Nations set up a Common Regime through Decision 391, creating national regulations geared towards the access and use of genetic resources and traditional knowledge associated to biodiversity by means of obtaining the prior informed consent and mutually agreed terms.

Given the fact that the strengthening of scientific and technological capacities in the Andean Community is one of the main objectives of the Regime, it was decided to conduct a case study in Colombia, not only because the country is a part of this regional community and is bound by all legal implications of Decision 391, but also because it is a megadiverse country.

The selected project describes the state of the art of biotechnology research, with the biological resources represented by a microorganism of the genus *Lactococcus* sp. and its levansucrase enzyme by-product which could have a real or potential use.

The entities in charge of the implementation of this initiative are the National University of Colombia (UNC) through the Institute of Biotechnology, the Research Vice Rectorate and the National Juridical Office, as well as government institutions, namely: the Regional Autonomous Corporation of Cundinamarca (CAR), the Ministry of Environment and Sustainable Development (MADS), and the National Natural Parks of Colombia (PNN).

The analysis of this case study, which still ongoing, offers important lessons for countries seeking to ensure a fair distribution of the benefits derived from their biodiversity as well as their genetic resources. Thus, it is crucial and decisive to suggest that in order to fulfill this premise, the process of strengthening endogenous capacities in science and technology must be improved. It is by accomplishing this that the legislation objectives concerning the access to biodiversity will be achieved.

Nemogá-Soto, G.R. and D. A. Rojas Díaz. 2013. Research on a microorganism of the genus *Lactococcus* sp., Institute of Biotechnology, National University of Colombia. In: Rios, M. and Mora, A. (Eds.), **Six Case Studies in Latin America and the Caribbean: Access to Genetic Resources and Benefit Sharing.** IUCN- UNEP/GEF-ABS-LAC. Quito, Ecuador. Pp.15-23.

2. Contractual Agreements

The Obligations and commitments for those implementing the biotechnology project have been detailed in accordance to the provisions of Contract 49, signed in 2012, and pertaining to the access to a by-product for purposes of industrial application and commercial use. Government institutions may follow-up on the project's activities on the basis of the data presented and applying the parameters contained in Decision 391.

2.1 Obligations and permits for scientific research

According to Resolution CAR 383, of August 13, 2001, the obligations derived from the permit consist on submitting the following:

i. Partial or final reports in accordance with the established schedule.
ii. Ratio of samples collected.
iii. Copy of the deposit confirmation.
iv. Report that describes the method of disposal of unused samples.
v. Registration of biological collections in the Alexander von Humboldt Institute.
vi. Copy of the publications.

2.2 Obligations of the access contract for a by-product with industrial application purposes

According to the parties participating research, it is agreed that Contract 49, pertaining to the obligations of the access contract for a by-product with industrial application purposes and commercial use of a levansucrase enzyme complex that has been biochemically isolated and identified from the native microorganism *Lactococcus lactis* and in charge of the synthesis of a biopolymer derived from sucrose. The contract establishes a term of 10 years and describes the obligations of the parties:

Obligations of the National University of Colombia:

i. Mention Access Contract 49 and name of the genetic resource in question in publications derived from the research.
ii. Submit to the Ministry of Environment and Sustainable Development as well as to other stakeholders, those results of research which are not confidential.
iii. Provide the Ministry of Environment and Sustainable Development with reports on the industrial and commercial application of the by-product, presenting one report every year as well as one at the end of the contract. The reports must comply with the guidelines established in Decision 391.
iv. Comply with the fair benefit-sharing agreement pertaining both, monetary and non-monetary benefits.
v. Store the microorganism in a deposit or strain bio bank.
vi. Inform the Ministry of Environment and Sustainable Development as well as the National Support Institution (INA) on the progress of the contract.

vii. Forward the research and publications derived from the activities of the Project.

viii. Disseminate non-confidential information to the database of the Institute of Biotechnology at

UNC. Obligations of INA correspond to the Technological University of Pereira:

i. Accompany and participate with the UNC in access activities.

ii. Collaborate with the Ministry in monitoring and control activities.

Obligations of the Ministry of Environment and Sustainable

Development:

i. Ensure the compliance with contract obligations.

ii. Evaluate reports and issue concepts.

3. Project and research activities description

3.1 Collection Activity

The environmental authority granting permission to conduct the research study is the CAR, in accordance with Resolution 383 of August 13, 2001. The objective is to isolate and identify a microorganism of the genus *Lactococcus* and check its enzymatic activity to generate the production of a natural-origin polymer. Resolution 383 states that:

i. The collection of soil samples is conducted in a private estate located in the municipality of La

Calera, Cundinamarca.

ii. The samples are analyzed at the Institute of Biotechnology of the UNC.

3.2 Access to genetic resources

Upon revision of Patent No. 2333599 registered at the Spanish Patent and Trademark Office (worldwide. espacenet.com), the following information was found in relation to the microorganism:

i. The project identified a method for the production of a sucrose polymer (levan) through a strain of the species *Lactococcus lactis*.

ii. The biopolymer can be used in the pharmaceutical industry as a plasticizer, thickener, stabilizer, dispersant, film-forming, disintegrant, blood plasma substitute, lubricating agent and prebiotic.

iii. The biopolymer can be used in the food industry as a thickener, plasticizer; stabilizer, dispersant, fiber and a substitute for fat, oil or carbohydrates which are ether or ester-based.

iv. The biopolymer can be used in: products obtained by extrusion for forming films which are suitable for producing flexible and biodegradable packaging which is ether or ester-based; disposable biodegradable products made by injection or molding which are ether or ester-

based; and in the production of flocculent agents for water treatment.

4. Detail of benefits included in the agreements

Upon revision of Contract de Access Contract 49 of 2012 for a By-product with Industrial Application Purposes and Commercial Use, signed by the Ministry of Environment and Sustainable Development and the National University of Colombia, hereon referred to as Contract 49, and through a personal communication with José Manuel Martínez (2012), officer of the Research Vice Rectorate, the following benefits were identified:

4.1 Non-monetary benefits

i. Facilitate the access to microorganisms of the genus *Lactococcus* kept in the bio bank.
ii. Conduct two workshops, one in the first year of Contract 49 and another in the third year, directed to the environmental authorities, with the objective of demonstrating the importance of biotechnology and its relationship with sustainable use of the genetic resources of the country.

4.2 Monetary benefits associated to industrial property

In the case the UNC obtains a patent in any country, the product and/or procedure obtained or developed from the access to the by-product which is the object of Contract 49 and for which a license were issued for third-party use, shall pay the Ministry of Environment and Sustainable Development an annual 10% of the total revenues perceived on account of the license.

Once the contract is completed, the UNC will not use the by-product for any purpose or claim intellectual property rights over them.

4.3 Monetary benefits associated with the commercial exploitation

In relation to the commercial or industrial use of the products and/or processes developed or derived from the access to the by-product which is the object of this contract and which are not protected by patents, the UNC shall pay to the Ministry of Environment and Sustainable Development an annual fee of 10% of the total amount of royalties received.

4.4 Benefits generated and shared to date

The information regarding the benefits generated and distributed to this date was collected in an interview with Gustavo Buitrago, co-inventor of the patent and professor at the Institute of Biotechnology of the National University of Colombia (Buitrago com. pers. 2012 y 2013).

Buitrago mentions the absence of benefit sharing up to this point, because no license has been granted for the commercial use of the research results. However, the Institute of Biotechnology signed two agreements with the company PROCAPS a few years back.

The first of these agreements was signed in 2002 and it consisted on determining if it was possible to make biopolymer capsules. Hence, the company funded researchers with 20 million Colombian pesos (US$10,500 at an exchange rate of 1904.76 Colombian pesos per dollar) and the Institute of Biotechnology contributed with its prior knowledge and the biopolymer.

Since there were positive results from the first agreement, the signing of a second agreement was decided in 2003 with the goal of building a pilot plant for biopolymer production. This time PROCAPS funded the construction of the pilot plant with 1,300 million Colombian pesos (US$ 682,501 at an exchange rate of 1904.76 Colombia pesos per dollar), and the size of the industrial plant was also determined. The capsule production was not viable from an economic standpoint, and this was the reason why the pilot plant is partially dismantled at the company's facilities. If a sound business plan had been achieved, PROCAPS would have had preference in the licensing of the patent.

5. Scope and status of project activities

5.1 Research status

Currently, the research status shows that markets for polymers are still being explored, and the research on identifying new applications is advancing (Buitrago com. pers. 2012).

5.2 Traceability and monitoring mechanisms

In accordance with Contract 49 it is stipulated that:

i. Publications are a monitoring tool.

ii. Four reports on the progress of activities must be submitted, one each year. It must be clear that: "Such reports shall be elaborated in accordance with the authorized access activities and the obligations stipulated in this contract" (Clause 11).

5.3 Impact on local socio-economic and/or institutional conditions

Information regarding the impact on local socio-economic conditions and/or institutional was collected based on interviews with Gustavo Buitrago, co-inventor of the patent and professor at the Institute of Biotechnology of the National University of Colombia, and Carlos Ospina, specialist of the Ministry of Environment (Buitrago com. pers. 2012 y 2013; Ospina com. pers. 2013).

i. For the UNC: financial support in the construction of a pilot plant; issuing of publications; implementation of cooperation agreements with other educational or research institutions; funding for participation in or organization of academic events; strengthening of the infrastructure for the collection of microorganisms; donation of lab equipment for the Institute of Biotechnology, and creation of job opportunities for graduates of their academic programs.

ii. For the Ministry of Environment and Sustainable Development: institutional reorganization and negotiating capacities in access contracts for commercial purposes.

5.4 Information regarding the request for Intellectual Property Rights and its status

The patent has been granted in Spain, France and the UK. The request has been withdrawn in Japan (2006546384) and the paperwork is still going on in the United States (US2007141667 A1) (Buitrago com. pers. 2012).

5.5 Description of conflicts or agreements reached

According to interviews with Gustavo Buitrago and Carlos Ospina data was collected regarding the conflicts which came up and the agreements reached during the duration of the project (Table1), thus finding solutions for situations that contributed to the process to move on with greater efficiency (Buitrago com. pers. 2012; Ospina com. pers. 2013).

Table 1. Conflicts and agreements during the project for biotechnology related to the species *Lactococcus lactis* and its levansucrase enzyme by-product.

Conflict	Agreement
Lack of systematization of the verbal agreements Between the National University of Colombia and the Ministry of Environment and Sustainable Development.	Minutes for the meetings have been elaborated for the last two years.
Research stagnation due to the precautionary measure imposed by the Ministry of Environment and Sustainable Development.	Signing of Contract No. 49 for commercial research purposes includes research on possible uses of biopolymer.
Disinformation between the Institute of Biotechnology and the Vice Rectorate of Research of the National University of Colombia regarding the request for access to genetic resources.	The Vice Rectorate of Research of the National University of Colombia participated in the negotiation process, legally supporting the Institute of Biotechnology and taking on the responsibility for the procedure of access to genetic resources.

6. Lessons Learned

Among the lessons learned, particularly due to the legal complexities and difficulties encountered during the project, the following can be highlighted:

i. Experience and initial setting of parameters for contracts for access to genetic resources with commercial purposes.

ii. Specialized management of the National University of Colombia in relation to PEFIC contracts for access to genetic resources.

iii. Recognition of the complexity and high degree of specialization required for the procedures to obtain access to genetic resources, where the creation of a group of access to genetic resources in the Ministry of Environment and Sustainable Development is a strategic action.

iv. Need for explanatory guides for the users of the regime of access to genetic resources.

v. It must be pointed out that at the moment there are still no perspectives regarding access and benefit sharing, or regarding the impact on the socio-economic conditions of the local population.

7. Bibliography

Contract 49. July 16, 2012. **Access to a By-product for Purposes of Industrial Application and Commercial Use.** Signed by: Xiomara Sanclemente Manrique (Director of Forests, Biodiversity and Ecosystem Services, Ministry of Environment and Sustainable Development) and Alexander Gómez Mejía (Vice Rector of Research, National University of Colombia). Bogotá, Colombia. 11 pp.

File 2571. **Permit for access to genetic resources and its by-products.** National Environmental Licensing Authority. Read and reviewed in 2013. Bogotá, Colombia. 463 pp.

8. Websites

Spanish Patent and Trademark Office. 2013. **Patent No. 2333599: Biopolymer based on Lactococcus lactis, NRRL B-30656, process for culturing Lactococcus lactis NRRL B-30656 and process for preparing the biopolymer.** Online at:
<http://worldwide.espacenet.com/publicationDetails/originalDocument?FT=D&date=20100224&DB=worldwide.espacenet.com&locale=en_EP&CC=ES&NR=23335993&KC=T3&ND=4>
Last viewed: July 30, 2013.

9. Interviews

Buitrago, G. Com. pers. 29/10/2012 y 19/02/2013. Professor of the Institute of Biotechnology, National University of Colombia. **Co-Inventor of the patent 2 333 599: Process for the culture of *Lactococcus lactis* NRRL B-30656 for preparing a biopolymer.** Bogotá, Colombia.

Martínez, J.M. Com. pers. 29/11/2012. Administrative assistant, Vice Rectorate of Research, National University of Colombia. **Interview regarding Contract 49 of 2012 pertaining to the Access to a By-product for Purposes of Industrial Application and Commercial Use.** Bogotá, Colombia.

Ospina,C. Com. pers. 27/02/2013. Specialist, Direction of Forest, Biodiversity and Ecosystem Services, Ministry of Environment and Sustainable Development. **Interview regarding Contract 49 and its impact on local socio-economic and/or institutional conditions.** Bogotá, Colombia.

Case Study in Costa Rica

©Laboratorio, Fabio Hidalgo -

Jorge Cabrera
Medaglia

Access to genetic resources, fair benefit sharing of and legal analysis of the agreement among the National Biodiversity Institute of Costa Rica, the Harvard University and the University of Michigan

1. Introduction

This case study describes and analyzes the relationship of access to genetic resources and fair benefit sharing among the National Biodiversity Institute of Costa Rica (INBio), the Harvard University (Medical School) and the University of Michigan. Thus, the legal scenario is one of the "International Cooperative Biodiversity Group" (acronym ICBG), a collaborative group supported by various organizations in the United States of America, such as the national health institutes (www.icbg.org).

Within this context, we analyze the way in which the contractual relationship was established in terms of a fair distribution of the benefits provided, as well as its interaction with the relevant legal framework. For this reason, it focuses particularly on what were the mechanisms for monitoring and traceability during this experience.

From the information gathered, we examine the tools and institutional capacities of INBio for the follow up and monitoring of projects through which genetic resources are accessed and transformed. The institutional analysis is carried out with a specific contractual relationship, presenting general considerations on mechanisms to implement the follow-up of a binational project that must comply with international commitments.

The case development consists of three stages. The first describes the INBio and its Strategic Action Unit (SAU) for Bioprospecting as well as the general legal framework applicable to the work of benefit sharing. The second focuses on detailing the precedents and contractual arrangements established among the principal participants of the research consortium, including the stipulated benefit and the results obtained. The third deals with critical precisions related to the national implementation of some components of the Nagoya Protocol.

2. National Biodiversity Institute of Costa Rica: Overview and the Bioprospecting Strategic Action Unit

INBio is a non-governmental non-profit organization of public interest, which was created in 1989 with the objective of supporting the Costa Rican government in its efforts to preserve the biological diversity of the country. In this sense, its institutional mission is to promote greater awareness about the value of biodiversity in order to preserve it and improve the quality of life of humankind. This is why it bases its activities on the national strategy of conservation which is focused on three pillars, namely:

Cabrera Medaglia, J. 2013. Access to genetic resources, benefit sharing and legal analysis of the agreement among: the National Biodiversity Institute of Costa Rica, the Harvard University and the University of Michigan. In: Rios, M. and Mora A. (Eds.), **Six Case Studies in Latin America and the Caribbean: Access to Genetic Resources and Benefit Sharing. IUCN-UNEP/GEF-ABS-LAC. Quito, Ecuador**. Pp. 25-63.

i. *Saving* involves the *ex situ* or *in situ* conservation of representative samples of Costa Rican biodiversity, and it is an activity which is carried out by the State as it is its direct responsibility, even with the support of private initiatives that contribute with this effort.

ii. *Knowing* implies having information related to: ecology; species diversity; taxonomy, and ecosystems in the country. INBio develops all these activities jointly with the National System of Conservation Areas (SINAC).

iii. *Using* represents the sustainable use of biodiversity resources, applying the information generated and systematized for the purposes of research, education or tourism. Thus, this activity is conducted by the SAU for Bioprospecting of the INBio since it is dedicated to the systematic search of biological diversity with industrial potential.

2.1 Strategic Action Units

INBio is organized into strategic action units, which carry out activities in five major thematic areas:

i. National inventory of biodiversity: it generates information on species, taxonomy, distribution and natural history. To date, the INBio has a collection of over three million specimens, mainly consisting of: plants, arthropods, macrofungi and microfungi. Each specimen has a barcode identification, including the collection and taxonomy data of the species.

ii. Bioinformatics: it systematizes and manages all the information generated by the SAU of the INBio in a corporate database called ATTA, and it is available to the public in the institutional electronic portal.

iii. Communication and education: it promotes bioliteracy and the use of biodiversity information for intellectual and spiritual purposes. The implementation is mostly done by the *INBioparque* where domestic and foreign people have an interactive experience with biodiversity information.

iv. Biodiversity management: it promotes the development of planned processes in the area of biodiversity management and conservation, while sharing the coordination responsibility with SINAC. The most important products of this collaboration are reflected in the elaboration of the National Strategy for Biodiversity as well as in the ecological studies of protected areas which are a foundation for decisions related to species and ecosystems.

v. Bioprospecting: it seeks the sustainable use of biodiversity, particularly of genetic resources and organisms with a potential biochemical use.

2.2 Institutional activities and alliances

Most INBio activities are developed in partnership with academic institutions and other research centers, often linking science and legislation, which is why bioprospecting is defined as: “The systematic search, classification and research –for commercial purposes– of new sources of chemical compounds, genes, proteins, microorganism and other products with a current or potential value, and which can be found in biodiversity” (Biodiversity Law 7788 of Costa Rica, from April 30, 1998, Article 7, Section 3).

INBio has set up over 50 agreements in the bioprospecting area with industry and academia, acquiring an extensive experience in executing projects involving high technology, lab equipment and staff training. It has also attained important achievements in the established North-South contractual cooperation.

The agreements for basic research or bioprospecting are carried out by the SAU in charge, thus guaranteeing: the traceability of biodiversity resources, the sustainable use and fair benefit sharing. If a product derived from biodiversity were to be positioned in the market, the benefits would be shared –in accordance with previously agreed terms– among the partner, INBio and the suppliers of the resource.

Whenever access is attained solely in protected areas of the State, the commitment of INBio with the Ministry of Environment and Energy (MINAE), the agreement shall be referred to and 10% of the research budget negotiated with the industry, as well as 50% of the total amount of royalties received shall be transferred. This will not be applicable in the case of academic partners.

Bioprospecting develops its activities around processes that are interrelated but also interdependent. For this reason, when the access takes place in private natural areas, the fair distribution of benefits is carried out in accordance with the Law of Biodiversity, with INBio negotiating up to 10% of the research budget and a 50% of the royalties resulting from the sale of a product obtained from the use of biological resources.

3. Development of negotiations and strengthening of the Bioprospecting Strategic Action Unit

With regard to the business development of the Bioprospecting SAU, INBio has managed to consolidate an interdisciplinary team of specialists and external consultants in charge of:

i. Defining the supply and business strategy.
ii. Identify opportunities with companies, foundations and research centers.
iii. Establish and maintain contacts with existing and potential partners.
iv. Develop negotiation processes, requiring an average of nine to 12 months.
v. Elaborate confidentiality agreements.
vi. Elaborate material transfer agreements (MTA acronym), a work plan and an agreement for scientific collaboration. The latter is unique, since it is used throughout the process, and so it varies according to the partner and the type of project to develop.

The coordination of each study is performed by a group of scientists –represented by external consultants– and the team of bioprospecting researchers, who are in charge of the negotiations and the completion of projects. This team of people propose both new ideas, and responses from the Bioprospecting SAU to the demands of academia or the industry.

With regards to the strengthening of the Bioprospecting SAU, the objective is the optimization of logistics, infrastructure and equipment, as well as the continuous training of the staff regarding cutting-edge technology. Likewise, projects are developed which bring an added value to scientific information on biodiversity because this makes it possible to access new sources of funding and establish scientific collaboration agreements or contracts for basic or advanced research in better negotiation conditions.

Also in terms of strengthening of the SAU, there have been actions geared towards the establishment of research and development projects with the national industry, applying biodiversity-based experience to small businesses. This action is carried out under the framework of the INBio/IDB/MIF Non-Reimbursable Technical Cooperation Agreement, in which the Bioprospecting SAU maintains a permanent supply of scientific services with the Costa Rican entrepreneurial sector in order to develop innovative products stemming from biodiversity.

This context of actors involved in the Bioprospecting SAU applies to: promoting the sustainable use of biodiversity, supporting economic development and improving the quality of life of Costa Ricans. There are also efforts on the way for the obtainment of funds to carry out projects with the small and medium national enterprises, as a way to transfer the knowledge and experience gained with large companies. Among the principal activities with national impact of INBio through this strategic unit, we find: chemical prospection, biotechnological prospection, sample collection and database development.

3.1 Chemical prospecting of biodiversity

In the chemical prospecting process, activities are carried out for the systematic search of molecules, compounds, chemical elements and/or secondary metabolites, which may be found in extracts or fractions obtained from the samples of plants, marine organisms, micro fungi and insects. The Bioprospecting SAU conducts these activities in a laboratory equipped with high technology, where it is possible to obtain extracts or semi-pure fractions on an industrial scale (with BioXploreã technology), as well as to isolate and identify compounds of interest to the pharmaceutical and agricultural industry.

Chemical prospecting is one of the most consolidated activities, because it has equipment; infrastructure; a highly experienced staff, trained by partner industries; and experience in numerous projects involving samples and various protocols. The agreements with the pharmaceutical companies Merck & Co., Bristol-Myers Squibb and Eli Lilly & Co., as well as scientific collaboration with the Universities of Cornell and Harvard, both institutions of international renown, have enabled the development of the internal capacity of the Bioprospecting SAU. For this reason, today it is recognized for its ability to negotiate contracts with both the national and international private sector, as well as with academia.

3.2 Biotechnological prospecting of biodiversity

The application of biotechnology for biodiversity prospecting, as in the chemical case, is connected to contracts with industries which have contributed to the infrastructure and equipment required.

The first steps in the use of biotechnology for biodiversity prospecting were taken in 1995, with the research of potential active compounds in micro fungi within the framework of the INBio-Merck project. A relation was established with Analyticom and INDENA, a company from Italy, during 1996 and the microbiology laboratory was expanded and biological activity trials were initiated.

In the period from 1996 to 1998, other contracts were signed with Recombinant Biocatalysist, which subsequently became *Compañía Diversa* and then *Verenium*. These contracts made it possible to establish the molecular biology laboratory. Currently, this company dedicated to the transfer and implementation of protocols related to property, extracts genetic material from bacteria growing in extreme conditions. In particular, it analyzes samples obtained from protected areas of the country.

The collaboration agreements mentioned above, as well as other relevant ones, allow the Bioprospecting to have four fully equipped laboratories for the purposes of: chemistry; microbiology; molecular biology, and mycology. Since INBio has access to cutting-edge technology, it has a good projection in the development of diverse research studies and it provides high quality services to national and international industry.

3.3 Biodiversity Sample Collection and Management

The collection of samples for basic research projects carried out by the Bioprospecting SAU, was initially conducted with the support of taxonomists from the National Inventory Program. However, when activities increased, people from INBio specialized in collecting the material required by the chemistry and biotechnology laboratories.

Currently, the research group is made up of professionals and field assistants whose responsibility is to collect a variety of plants, effluent water and marine organisms. The training and expertise of this team optimizes the time of scientists who request and receive the samples in a timely manner according to established protocols.

In the case of sample management, a database is kept up to date with taxonomic identification, date and collector's name, the exact collection location and any additional information required. All this wealth of references makes it possible to return to the exact area of collection, especially when a restocking request is received from a company or research center which previously held or currently holds a contract.

The experience and the level of knowledge that the sample management team has acquired has become an essential tool to fulfill the commitments made in the various contracts and to provide an attractive offer to potential partners.

3.4 INBio Databases

The information related to the samples collected, places of collection, collectors and relevant associated information is entered into databases developed individually for each project. One example of the activity of INBio during the period from 1991 to 2012, can be seen in 42 contracts considered important due to their high scientific level and their field of application (Table 1).

The Bioprospecting SAU has access to the ATTA database of INBio, which offers free access to the public, but also has its own system with restricted access for the purposes of traceability, intellectual property rights and reporting, due to each project having its own particular research.

There is an IT expert in the unit, who is responsible for generating each particular database, integrating all the information produced by each one of the projects and elaborating the reports required by the researchers.

Table 1. Main INBio contracts for research collaboration with industry and academia during the period from 1991 to 2012.

Industrial or academic partner	Main purpose	Field of application	Period
Universidad de Cornell	Institutional capacity development	Chemical Prospection	1990-1992
Merck &	Plants, insects and microorganisms health	Human and animal	1991-1999
"British Technology Group" y ECOS	*Lonchocarpus felipei,* Source of DMDP*	Agriculture and pest control	1992-2005
Universidad de Cornell, Bristol Myers, NIH e "International Cooperative Biodiversity Group"	Insects	Human health	1993-1999
Givaudan Roure	Plants	Fragrances and aromas	1995-1998
Universidad de Massachusetts	Plants and insects	Agriculture	1995-1998
Diversa VERENIUM	Culturable bacteria DNA	Industrial application	1995-to present
INDENA SPA	Plants*	Human health	1996-2005
Phytera Inc.	Plants	Human health	1998-2000
The University of Strathclyde	Plants	Human health	1997-2000
Eli Lilly	Plants	Human health and agriculture	1999-2000
"Akkadix Corporation"	Bacteria	Agriculture	1999-2001
Follajes Ticos	Palm	Ornmental improvement	2000-2004
La Gavilana S.A.	Microorganisms	Agriculture	2000- to present
Laboratorios Lisan S.A.	Plants	Human heatlh and phytodrugs	2000-2004
Bouganvillea S.A.	*Quassia amara*	Agriculture	2000-2004

Agrobiot S.A.	Plants*	Ornamental improvement	2000-2004

Industrial or academic partner	Main purpose	Field of application	Period
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	DPI management	2002-2006
Industrias El Caraíto S.A.	Nutraceuticals	Human health	2001-2004
Medical School (Harvard University), “International Cooperative Biodiversity Group” R21	Endophytes	Human health	2003-2005
University of Panama and OAS	Plants	Human health	2003-2004
Medical School (Harvard University) and the “National Cooperative Drugs Discovery Group” (NCDDG)	Endophytes	Human health	2005-2008
“Ehime Women Collage”	Plants	Human health	2005-2008
Laboratorios Vaco S.A.	Microorganisms	Industrial applications	2005-2011
Medical School (Harvard University) and “International Cooperative Biodiversity Group”	Endophytes, lichens and marine organisms	Human health	2005-2009
Pfizer Institute	Microorganisms	Human health	2005-2006
PNUD, BIOTRADE, UNCTAD, CAF	Implementation of the National Bio-Commerce Program	Bio-Commerce	2005-2006
CONICIT	Spiders (ADN)	Molecular taxonomy	2004-2005
CONICIT	Plants	Human health	2005-2006
“Korean Research Institute of Bioscience and Biotechnology” (KRIBB)		Plants	2008-to present
	Human health		
Medical School (Harvard University) and “Medicine for Malaria Venture” (MMV)	Endophytes	Human health	2007-to present

Industrial or academic partner	Main purpose	Field of application	Period
CONICIT	Microorganisms	Industrial applications	2008
CONICIT	Establishing trials involving the *Aedes aegypti*	Human health	2007-2010
Spanish National Research Council and CRUSA Foundation	Microorganisms	Enzymes and industrial applications	2008
Spanish National Research Council and CRUSA Foundation	Microorganisms	Human health	2008
IDB Chilean Fund and the Adolfo Ibáñez-Octantis University	Institutional capacity development	Venture management	2008
University of Michigan y Harvard University (ICBG II 2009-2013)	Fungi and microorganisms	Human health and bioenergy	2009- to present
Florex de Costa Rica	Microorganisms and plants	Cleaning products	2010 - to present
Pharma Mar	Marine Organisms	Human health	2012 - to present

4. INBio Sponsorship for the "International Cooperative Biodiversity Group": bioprospecting applied to human health

The case study is based on a project entitled "Discovery of natural product-based drugs from the Costa Rican biota" which was a research project proposed by INBio in 2005, sponsored by the "International Cooperative Biodiversity Group" and funded by the U.S. National Institute of Health (NIH). The research is conducted within the framework of four programs implemented by: the Harvard University, the University of Michigan and INBio, with Dr. Jon Clardy, Professor of Biological Chemistry and Molecular Pharmacology at Harvard University, serving as lead researcher.

The first phase of the research was carried out during the period from 2005 to 2009, which is the typical duration of such consortia. Subsequently, a second proposal was submitted to the National Institute of Health in 2009 and was approved. Thus, a second "Grant" was obtained (Prime Award No. 2 TW00740405), which differs from the first in that the lead researcher is from the University of Michigan and bioenergy was included as a new project target.

Is worth mentioning that this second contract, unlike the first, has some different characteristics such as the participation of two private companies and three academic partners, generating contractual arrangements of varying complexity. The expected result in this new phase, focuses on compounds with potential for the treatment of human diseases such as cancer, neurodegenerative diseases and malaria.

In this scenario, this project was selected for legal analysis because it involves the participation of several institutions and the handling of samples at various centers as a strategy to identify compounds with potential. Also, special attention is required for traceability. Some of the reasons upon which this research consortium is based take into account several particular factors, five of which are essential in the achievement of its goals and focus on biodiversity, human talent and institutional quality. The following is a detailed analysis of each of these factors.

4.1 Biological wealth and diversity of ecosystems Costa Rica

Costa Rica comprises a total of 51,100 km² of continental land, which represents 0.03% of the world's surface, and it possesses 589,000 km² of territorial waters, and it is known for being the home of approximately 4% of the world's biodiversity. Legally, 25% of the territory is under some form of protection, and it is estimated that the entire surface holds about 500,000 species of plants, animals and microorganisms, but only 18% of them have been documented.

The country is divided into 11 conservation areas and has a total of 171 protected areas whose ecosystems and biodiversity are known to the INBio through the Inventory Program and the Bioprospecting SAU. Nevertheless, there is still a high percentage of unexplored biodiversity in terms of its taxonomy and potential applications.

One of the cases which requires further exploration is the case of microorganisms that inhabit a variety of ecological niches, ranging from intestinal cavities of marine and terrestrial organisms, to soils, sea beds, and plant tissues. For this reason, the search for potential uses of this rich biodiversity in therapeutic solutions for incurable diseases was set as a target.

4.2 Biological resources used as source of new compounds

The results obtained in previous projects with biodiversity resources have been used as a guide for obtaining new compounds, particularly in projects implemented by the Bioprospecting SAU which require biological elements as a source of genetic and biochemical resources such as plants, fungi, insects, environmental samples, and marine organisms.

The most interesting samples are of the flora and the environment; the latter stand out as a source of metagenomes for the biotechnological industry. DNA has also been extracted, and proteins and enzymes for international industrial application have been discovered. These are the first products of INBio to generate monetary benefits in favor of conservation.

With respect to microbial diversity in itself, more information is needed and efforts are on their way for the taxonomic identification of micro fungi, principally of Ascomycetes. This is how the project pertaining to this case study –as others developed with the Harvard University and national enterprises– has increased collection, particularly of Endophytes. Overall, the goal is to learn more about national microbial diversity and enhance its use in human health and its animal and plant applications.

4.3 Experience and knowledge of INBio

INBio has a vast experience in search, identification and processing capabilities for biological resources, as well as capabilities to develop biological tests that determine activity. Thus, for this case study, this institution and other members of the consortium represented by research institutes of the U.S., have joined together to discover therapeutic agents from natural products attempting to achieve the following:

i. Specific objectives pertaining to the products that they wish to obtain, such as compounds with anti-cancer, anti-neurodegenerative and anti-malaria activity.

ii. Preliminary results with the "planning grant (R21)" funded by the Institute of Health of the United States of America, with the Harvard University running and using fungal endophytes as a biological resource.

The foundation required for the project prompted a considerable effort to define the biotopes to be the source of genetic and biochemical resources, focusing on those that must be explored for the purposes of compound extracting and environmental conservation. In this context, the areas selected were mainly: mangroves, moorlands, ancestral territories and water ecosystems where epiphytes grow.

Another focus of the project was to study metagenomes of cyanobacteria, actinomycetes fungi and lichens. In this case, the research requires a collection of microorganisms and derived natural products, and it needs to determine its processing and / or culture isolation considering these are organisms which have scarcely been studied.

The planning for the INBio project involved taxonomists from the National Inventory Program and researchers from the Bioprospecting SAU; specialists from the Centre for Research in Marine Sciences and Limnology of the University of Costa Rica (CIMAR), and experts from the Universities of Harvard and Michigan.

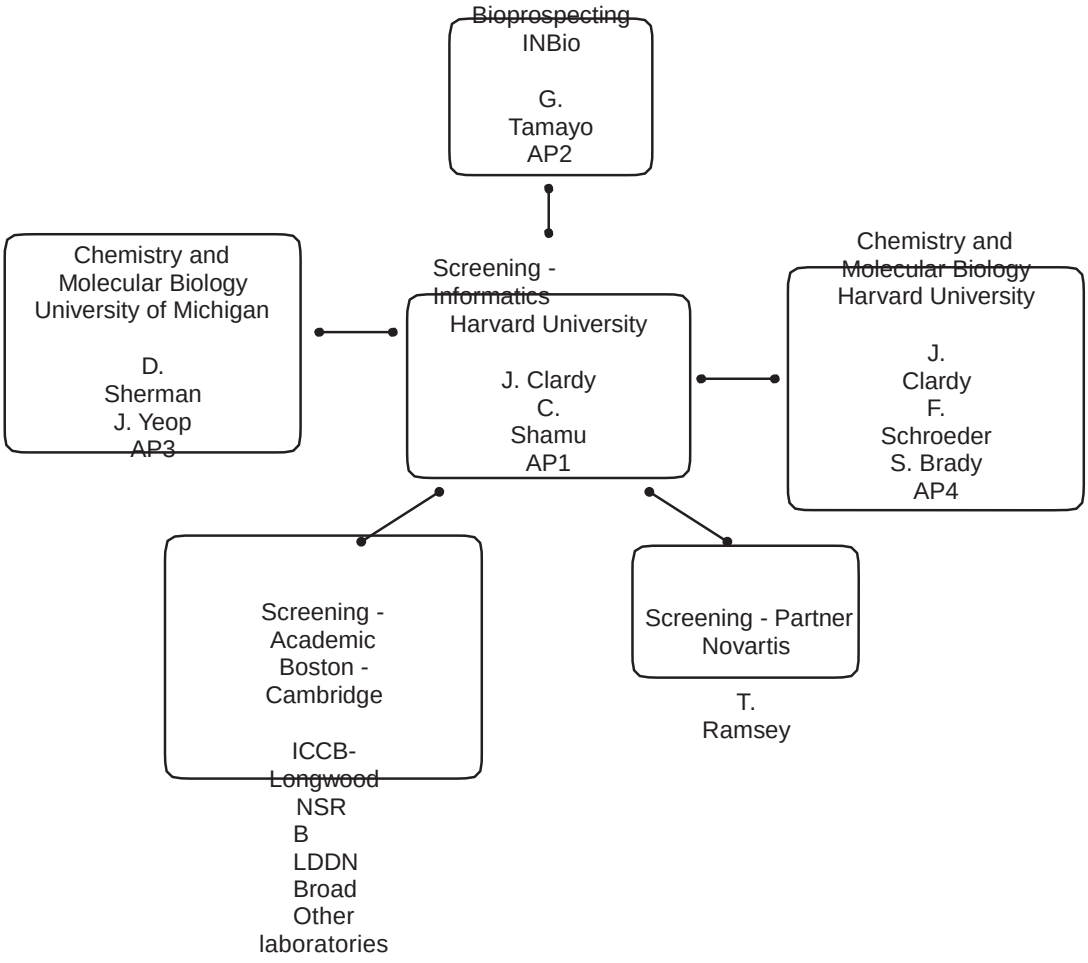
5. Access and research activities

The activities of Project “Discovery of natural product-based drugs from the Costa Rican biota”, were divided into four associated programs (APs): two in the Harvard University (AP1 and AP4), one in the University of Michigan (AP3) and one at the INBio (AP2).

The assignation of the APs was conducted according to the responsibility that each of the participant institutions assumed (Graphic 1), which meant distributing implementation activities in correspondence with their capacities, human talent and cutting-edge technology (Graphic 2).

5.1 Associated Program 1 (AP1)

AP1 is located at the Harvard Medical School of the Harvard University. Its responsibilities are: conducting biological trials, centralizing the information for each program, distributing the fractions to other laboratories for other screenings, and managing the project at a global level. In this respect, AP will receive pre-fractionated extracts and will distribute microplates with samples to the diverse academic and industrial laboratories.



Graphic 1. Assignation of responsibilities of Project “Discovery of natural product-based drugs from the Costa Rican biota”, conducted in programs associated to the experience and staff at each institution. Source: Martín com. pers. 2013, Bioprospecting SAU of INBio.

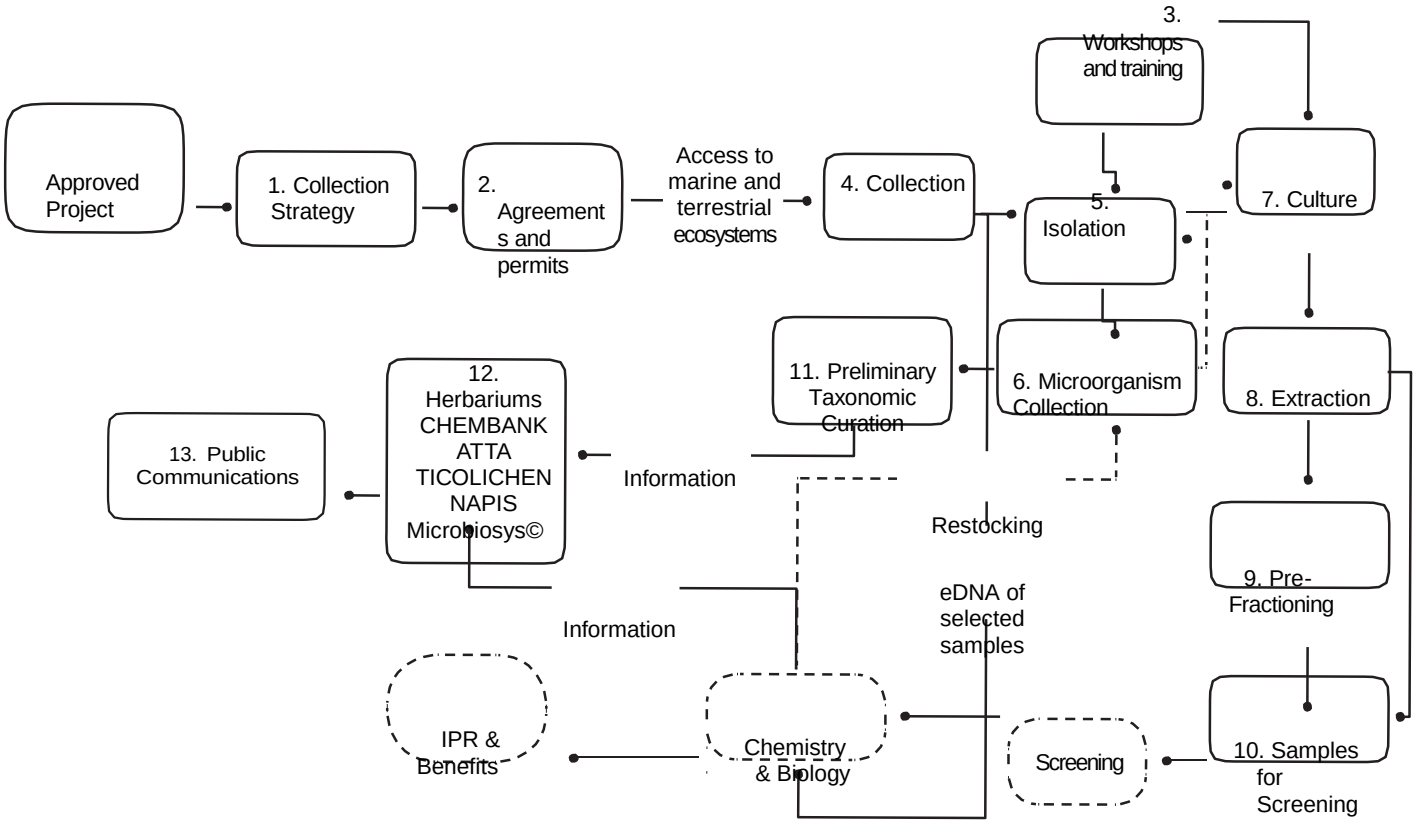
5.2 Associated Program 2 (AP2)

AP2 is located at INBio, and its responsibilities are: soliciting the permits for access to genetic resources in Costa Rica; collecting samples; coordinating sample collections with the University of Michigan and CIMAR; providing pre-fractionated extracts to executors of AP1; conducting projects involving endophytes and lichen microsymbionts (collection, culture, curation, extraction and pre-fractionation); organizing a myxobacteria project; work jointly with AP3 in order to jointly build capacities for studies of microorganisms such as actinomycetes and cyanobacteria; and collection environmental samples for DNA isolation.

5.3 Associated Program 3 (AP3)

AP3 is located at the University of Michigan, and its responsibilities are: cooperating with AP2 in the collection of marine samples, as well as in isolating marine actinomycetes, myxobacteria

and cyanobacteria; generating pre-fractionated extracts from cultures of actinomycetes, myxobacteria and cyanobacteria; and collaborating on small molecule chemistry, biosynthetic metabolic engineering and chemoenzymatic synthesis.



Graphic 2. Distribution of activities in Project “Discovery of natural product-based drugs from the Costa Rican biota”, each conducted by the corresponding AP institution. Numbered activities are conducted in Costa Rica or are the responsibility of the AP2. Source: Martín com. pers. 2013, Bioprospecting SAU of the INBio.

5.4 Associated Program 4 (AP4)

AP4 is located at the Harvard Medical School of the Harvard University, and its responsibilities are: structural isolation, purification and determination; studying and sequencing of DNA from environmental samples; and provide selected genes to the AP3 executor for biosynthetic studies.

5.5 Collection Activities

The collection strategy is coordinated with the AP, and each external partner or advisor must meet the activities established in the project, with the objective of exploring the metagenomics of environmental samples, cyanobacteria, actinomycetes, lichens and fungi. The sample management team at the Bioprospecting SAU will collect the biological material with the support of the administrative staff, since the first requirement is the Prior Informed Consent (PIC). Then the permits for access and use of genetic and biochemical elements from biodiversity are granted. Collection starts when the permit resolution has been issued and authorized by the Technical Office (TO) of National Commission for Biodiversity Management (CONAGEBIO). Once this has been obtained, those in charge will define the action plan based on the required samples and the locations previously established in the project.

The goal is to explore biodiversity which has been scarcely studied. This is why samples are collected from different biotopes in nine of the 11 conservation areas in the country, namely: the *La Amistad Caribe* Conservation Area (ACLAP); the *Tempisque* Conservation Area (ACT); the *Arenal Tempisque* Conservation Area (ACAT); the *Guanacaste* Conservation Area (ACG); the *Tortuguero* Conservation Area (ACTo); the *Cordillera Volcánica Central* Conservation Area (ACCVC); the *La Amistad Pacífico* Conservation Area (ACLAP); the *Osa* Conservation Area (ACOSA), and the *Arenal Huetar Norte* Conservation Area (ACAHN). On each trip, the team in charge of collection plans the location of the sites and the time when it is possible to identify specimens on site in coordination with biodiversity inventory experts.

When little known microorganisms are studied, taxonomic identification of morphological features is difficult, so molecular tools are often used specially in the case of species with therapeutic potential. The traceability of the samples and their associated information, is established in an ATTA-compatible information system. The system logs, for instance, the morphological taxonomy which is public dominion into the institutional database. The molecular information is restricted because ATTA requires tools for access by third parties.

The Prospecting SAU will develop a database of its own in order to back up all the project's information. At the same time, the AP2 is responsible for programming the interface that links the information from INBio to NAPIS, since this is the database suggested by the ICBG to follow up all the data produced by the research.

The focus of the study of little known microorganisms firstly reveals information about the microbial diversity of particular biotopes of the country. And while this information is used for the purposes of the project, eventually it will belong to the *ex situ* collection of INBio. Likewise, it can be used in other basic or bioprospecting research projects because the collection represents an added value for the national species inventory.

Regarding the study material, the project seeks innovative natural products through the use of advanced techniques and technologies such as metabolic engineering, chemoenzymatic synthesis, access to High Throughput Screening (HTS acronym) and structural elucidation. As such, the probability of a discovery for the pharmaceutical industry from biodiversity resources is low, and the expectation is to find –through comprehensive sampling and HTS– promising compounds that may be licensed by the industry in order to develop pharmaceutical products.

6. National legislation acosta Rica and legal framework for ABS

The following is a brief description of the Costa Rican national legislation applicable to activities of access to genetic resources for a prior and better legal understanding of the case.

6.1 Legislation related to the Biodiversity Act and Rules for Access

The Biodiversity Law (LB) 7788 of May 27, 1998 states that: "The terms of access to genetic resources has been regulated by Decree 31514-MINAE and its amendments" (*La Gazeta*, December 15, 2003); "General rules for access to genetic and biochemical elements and resources from biodiversity" (hereinafter referred to as the Rules for Access) are regulated by Decree No. 33697-MINAE, which provide regulations for the access to genetic resources under *ex situ* conditions, but have not been applicable for the case study.

In this legal context, the requirements and procedures for access to genetic resources and fair benefit sharing are regulated in detail. The legislation provides definitions for topics such as access to genetic and biochemical elements, bioprospecting, prior informed consent; innovation; and access permits (Art. 7). It also clarifies the ownership of genetic and biochemical resources of wild or domesticated biodiversity, declaring them of public domain (Art. 6), which means they belong to the State in an administrative capacity, and differentiating two different properties: that of the biological or organic resource and that of the biochemical and genetic resource.

6.2 Scope of application for ABS

The legislation applies to "...elements of biodiversity that are subject to the sovereignty the State, as well as the processes and activities carried out under its jurisdiction or control, regardless of those whose effects are manifested within or outside national jurisdiction. This law specifically regulates the use, management, associated knowledge, fair sharing of benefits and costs arising from the use of biodiversity elements "(Art. 3).

Article 6 (public domain) states that "...the biochemical and genetic elements of wild or domesticated biodiversity belong to the public domain. The State will authorize the exploration, research, bioprospecting, use and exploitation of biodiversity elements which constitute public domain property, as well as the use of all genetic and biochemical resources, by way of the Rules of Access stipulated in Chapter V of this Law".

In Article 62 and Article 69, it is mentioned that every research or bioprospecting program on genetic or biochemical material from biodiversity that is meant to be conducted in Costa Rican territory requires an access permit unless they fall into any of the exceptions contemplated by the Law under Article 4. Thus, this application relates to the access to human genetic resources, the exchange of genetic and biochemical resources, as well as the associated traditional knowledge deriving from traditional practices of indigenous peoples and local communities, which are not for profit.

Public universities had until May 7, 1999 to establish their own controls and regulations for nonprofit research involving access, but only the University of Costa Rica issued their corresponding regulation. In the case of the pharmaceutical, agricultural, biotechnological, ornamental and medicinal herb sectors –among the most important ones–, as long as they are accessing a genetic component they are subject to the application of the Law and they must follow the appropriate access procedures.

In summary, the scope of application encompasses all elements of biodiversity which are considered to be under the sovereignty of the State (Art. 3) and every research or bioprospecting program that is to be conducted in Costa Rican territory requires an access permit (Art. 69). Thus, access regulations apply to genetic resources in public or private lands, terrestrial or marine environments, ex situ or in situ conditions and in indigenous territories. Article 2 which refers to the scope of application of the Rules for Access, stipulates that these shall apply to genetic and biochemical wild or domesticated biodiversity elements, both *in situ* and *ex situ* which are under the sovereignty of the State, whether they are public or private property.

There is the possibility of establishing the procedures needed for getting a permit of access to *ex situ* collections by way of a separate regulation, provided these are duly registered at the Technical Office of the Commission (Art. 69). Said regulation can be found in Decree 33697-MINAE (*La Gaceta*, April 18, 2007).

The Law constitutes the CONAGEBIO and confers to it instrumental legal status as a decentralized entity of the Ministry of Environment and Energy (Art. 14). Its mandate is "formulating the policies and responsibilities stipulated in Chapters IV, V (Access to genetic and biochemical elements and protection of associated knowledge) and VI of the law and coordinating these with the various agencies in charge of the matter (Paragraph 2); as well as formulating and coordinating the policies for the access to biodiversity elements and associated knowledge, which will ensure an appropriate scientific/technical transference and a fair sharing of the benefits. For the purposes of Title V of this Law, such policies will be called Rules for Access (Paragraph 3).

The CONAGEBIO shall execute its agreements and resolutions and instruct regarding their procedures through the Executive Director of the Technical Office (TO) (Art. 16). The Commission should formulate policies on access and benefit-sharing, and may revoke the resolutions of the TO in the matter of access (Art. 14). The Commission will consist of government entities, such as: the Ministry of Environment presiding; the Ministry of Foreign Trade; the Ministry Health; the Ministry of Agriculture; the Costa Rican Institute of Fishing and Aquaculture; the National Guiding Committee; the Indigenous Bureau; the Peasant Bureau; the National Union of Chambers; the Costa Rican Federation for Environmental Conservation, and the Director of the National System of Conservation Areas (Art. 15).

In accordance with Article 62, it is CONAGEBIO responsibility to propose policies of access to genetic and biochemical elements of biodiversity both ex situ and in situ, acting as a body of mandatory consultation pertaining the protection request procedures for intellectual property rights over biodiversity.

The TO of the Commission is composed of an Executive Director and staff as indicated by the regulations of the law. Their main responsibilities are: processing, rejecting and overviewing the requests for access to biodiversity resources (Art. 17, paragraph A); coordinating with Conservation Areas, the private sector, indigenous peoples and peasant communities the issues pursuant to access (Art. 17, paragraph B); organizing and updating the registry of: requests of access to biodiversity elements and collections *ex situ* and of people – individual or institutional– engaged in genetic manipulation (paragraph C); and gathering and updating the rules of compliance for agreements and guidelines pertaining to biodiversity (paragraph D).

6.3 Procedure for access to genetic resources

According to Art. 71 of the Biodiversity Law, which refers to the characteristics and conditions of access permits, the requirements are determined differently for non-commercial research, but conclusive proof that there is no interest of profit must be provided. Also, according to Art. 9, the Rules for Access address basic research and bioprospecting equally, developing the TO formats for submission of documents and requirements in compliance with procedures established by Law (www.conagebio.com).

6.4 Basic requirements for access to genetic resources

The Law regulates the basic requirements for access, including: prior informed consent from the providers of the resource; a countersignature of such consent by the TO; the terms for technology transfer and benefit sharing, whenever these are available; the type of protection for associated knowledge that the representatives of the accessed location demand; the definition of the ways in which such activities will contribute to the conservation of species and ecosystems, and the designation of a legal representative in the country, when it involves individuals domiciled abroad (Art. 63).

Article 64 establishes the procedure to follow, since the request for access must include: the prior informed consent of the owner of the location where the activity will be conducted, the authorization of the indigenous community, if the location is in their territories; the authorization of the Director of the Conservation Area (art. 65); the right to cultural objection (Art. 66), and the registry of access rights and protection of confidential information, except for biosecurity (Art. 67).

In Section II of Chapter V of the law, there is a more precise regulation for the issue of permits for research and bioprospecting (Art. 69), which are given for a period of three years that may be extended. The permits are personal and non-transferable, and are materially limited to the genetic and biochemical elements authorized as well as to the area or territory expressly determined (Art. 70).

The access permits for research, bioprospecting or commercial use do not grant or delegate any rights. They merely allow for the activities to be conducted on the biodiversity elements which

have been previously determined. Likewise, the certificate of origin clearly stipulates: the possibility or prohibition for extracting samples, the periodical reports, the verification and control, the publicity and property of results, as well as any other condition applicable in accordance with the TO's opinion (Art. 71).

The requirements of the access request are basically consist of the following: the name and identification of the interested party or the identification of the representative acting on behalf of the interested party, the name and identification of the researcher in charge; the exact location and elements of biodiversity which will be studied, and a description of who is the owner, the manager or holder of the property; a descriptive schedule of activities, goals and objectives pursued; a confirmation of having made the declaration under oath, and a place for notifications and prior informed consent (Art. 72).

Registration of individuals or legal entities that carry out bioprospecting states that it does not grant any rights (Art. 73). Also, the TO will authorize agreements between individuals, whether national or foreign, or between them and the institutions registered for that purpose, who are considering access to genetic and biochemical elements (Art. 74). Additionally, there is the possibility of signing framework agreements between the CONAGEBIO, universities and other duly registered centers (Art. 74), and assigning up to 10% of the research budget and a 50% of the royalties to the Conservation Area, private proprietor or indigenous territory added to the expenses of the proceedings (Art. 76). If the TO authorizes the constant use of genetic material or biochemical extracts for commercial purposes, the interested party will be asked to obtain a concession for their exploitation (Art. 75).

The regulation affirms the institutional powers established by the law (Art. 5 of Decree 31154-MINAE), reiterating the diverse types of permits anticipated by the law: basic research, bioprospecting and commercial use. So, if any of these permits were to qualify for another, that is to say if from basic research the activity changed to commercial use or bioprospecting, and it ended up as an economic profit activity, the requirements for each specific case must be complied with (Art. 7). The regulations require the registration of the party interested in conducting the access activities (Art. 8) and it determines the requirements and documents to be presented, such as: the name and full identification of the interested party, including a place for notifications; those people or entities domiciled abroad shall designate a legal representative residing in the country and the type of permit they intend to initially request.

The requirements for an access permit for basic research, bioprospecting or commercial use (Art. 9) can be requested with a form and a technical guide (Art. 9, points 1 and 2). Once the information is complete, the interested party will obtain their authorization card and the prior informed consent may be negotiated (Art. 9.3) using the agreement template elaborated by the TO which has been validated (Art. 12), and queries in the field may also be done if deemed necessary. Additionally, point 9.4 stipulates the requirements for basic research or bioprospecting, and point 9.5 determines what is needed to get a commercial use permit.

The procedure, in terms of the regulations, is defined in Art. 10, which gives the TO a term of 15 calendar days to the interested party to submit the missing requirements or documents. In practical terms, this means 10 working days, after which the request is archived. Subsequently, there is a period of 30 calendar days to respond (Art. 10).

In the case of concessions, when procedures have requested access –on at least six different times in a period of five years– to the same genetic or biochemical resource for commercial use, the MINAE may be called upon to grant it (Art. 11). The resolution which approves or rejects the permit must be justified and once approved, the access permit is delivered along with the corresponding access passport, which authorized the interested party to enter the place where the access will take place.

It is established that the PIC requires the validation of the TO, who will issue the permit taking into account the principles and objectives of the Convention and the Biodiversity Law, as well as all the provisions of Costa Rican Law. The TO may make inquiries and ask the parties involved in the PIC for additional information (Art. 12). The resolution of approval will contain: the duration of the permit; the obligation of the interested party of depositing up to 10% of the research budget and 50% of the royalties in favor of the resources provider where applicable, as well as any other benefit or technology transfer that may be part of the prior informed consent; the obligation to present reports and their periodicity, and any other condition or restriction deemed necessary (Art. 13).

The requests and resolutions are published in the web site of the Commission after 8 working days, respecting trade secrets and the provisions of the Undisclosed Information Law (Art. 15). If the resolution of the TO is to deny the permit or if there were any inconformity on the part of the interested party or the resource provider, there is a period of three working days to appeal to the CONAGEBIO, entity which will exhaust all administrative possibilities (Art. 16). Similarly, the payment of administrative fees is stipulated (these have not yet been fixed through the respective decree, Art. 17).

If the materials are exported they must comply with the formalities of national law (Art. 18), and the TO will extend a certificated of origin or legal precedence (Art. 19, Rules for Access). Up to this date, a certificate has been issued for each request made by applicants to an access permit. In every case, the official interpretation is that this is done at the request of the interested party and it has been issued twice.

The TO will perform the tasks of verification and control, which it can coordinate with the provider of the resource and it may also conduct inspections on site (Art. 20). Likewise, the power to sign framework agreements with CONAGEBIO is stipulated (Art. 21) for *in situ* and/or *ex situ* access; as is the purpose of these agreements which is to facilitate the procedures and the process of obtaining the access permits. The capacity of the TO to authorize transfer contracts and agreements for designated materials between individuals involved in the access (Art. 22).

The maximum term for the permit is of three renewable years (Art. 23), and it may also be restricted or conditioned by a number of factors set out in Article 24, because sanctions are regulated and they include temporary suspension and even cancellation of the access permits in the event of a breach (Art. 27). Fines can be equivalent to 12 minimum wages in cases of unauthorized access or omission of the conditions of the permit (Art. 28). Eventually, granting the authorization might require the environmental feasibility of the National Technical Secretariat (SETENA) (Art. 26).

Transient No. 1 of the Rules for Access, amended by Decree 32066-MINAE (*La Gaceta*, November 2, 2004), expressly determined that “For genetic and biochemical elements of biodiversity maintained in *ex situ* conditions, and in a period of a year from the publication of this regulation he CONAGEBIO –with the support of experts and specialized technical staff– will

establish

the procedure for access to biodiversity elements and resources kept in *ex situ* conditions, in accordance with Art. 69 of the Biodiversity Law. While there are no regulations no access permits will be granted for bioprospecting or commercial use of material found in these conditions." Thus, a moratorium was declared on the granting of access permits for the purposes of bioprospecting or commercial use, allowing for the execution of this basic research project. Originally, the term given for the drafting of the regulations and its publication was of six months. This was modified by a reform of November 2, 2004 which extended the period to one year.

6.5 The case of *ex situ* collection

In response to Transient No. 1 of the Rules for Access, Executive Decree 33697-MINAE (*La Gaceta*, April 18, 2007) hereinafter referred to as the Regulation on Access to Genetic and Biochemical Elements and Resources from Biodiversity in *ex situ* Conditions, was issued.

From the publication of the Executive Decree, the access to genetic and biochemical elements and resources from biodiversity in *ex situ* conditions must comply with this regulation and to numeral 31514-MINAE where applicable (Art. 1). Thus, it applies to biodiversity components, whether these are: wild or domesticated; terrestrial; marine; endemic to freshwater or air; and in *ex situ* conditions, whether they are: individual or institutional collections; public or private; located in any part of the national territory (Art. 6, Political Constitution), or kept in a non-systematic form (Art. 5, Executive Decree).

Notwithstanding the provisions of Art. 4 of the Biodiversity Law, the biodiversity elements and resources in *ex situ* conditions which are used as organic resources are excluded from the application of this Regulation. They will continue to be regulated the Forestry Law 7575 of December 13, 1996 (*La Gaceta* No. 72, April 16, 1996) and its amendments; the Law of Wildlife Conservation 7317 of October 30, 1992 (*La Gaceta* No. 235, December, 1992) and its amendments; the Law of Creation of INCOPESCA 7384 of March 16, 1994 (*La Gaceta* No. 62, March 29, 1994) and its amendments; the Law of Fisheries and Aquaculture 8436 of March 1, 2005 (*La Gaceta* No. 78, April 25, 2005) and its amendments; the Law of Phytosanitary Protection 7664 of April 8, 1997 (*La Gaceta* No. 83, May 2, 1997) and its amendments, and the Seed Law 6289 of December 4, 1978 (*La Gaceta* No. 7, of January 10, 1979) (Art. 2).

Another case which has been excluded is the exchange of genetic and biochemical resources, as well as the associated knowledge resulting from nonprofit practices and customs, among indigenous peoples and local communities (Art. 4, Biodiversity Law). In addition, the access to genetic and biochemical elements and resources from domesticated animal biodiversity will be regulated in accordance with Transient No. 1 of the Executive Decree.

CONAGEBIO is the competent National Authority responsible for proposing policies regarding the access to genetic and biochemical resources and elements from biodiversity and their associated knowledge, while ensuring an adequate scientific, technical and technological transfer as well as a fair and equitable benefit sharing. In accordance with Art. 17 of the Biodiversity Law, the TO of this institution will be responsible for processing, approving, rejecting and controlling the requests for access to biodiversity in *ex situ* conditions and their associated knowledge. Also, the TO shall act as a focal point on the issue of access to genetic and biochemical elements and resources from biodiversity and the sharing of the benefits derived from the access to these before the Secretariat of the Biodiversity Convention (Art. 3).

The ex situ conditions refer to the permanence of the elements of biodiversity outside their natural habitats, including both systematized collections as well as non-systematized genetic and biochemical resources, kept by individuals or institutions, public or private. Thus, in order to have access to genetic and biochemical elements and resources in either of the two aforementioned ex situ methods, it is required for the interested party to obtain an access permit following the procedure established by this Executive Decree.

The *ex situ* genetic and biochemical elements and resources can be conserved: live in the field; in refrigeration chambers; frozen; through cryopreservation; *in vitro*, or dead in dry or humid conditions (Art 5). The owners or managers, whether they are individuals or institutions, public or private, or their representatives, must register their *ex situ* systematized collections with a form elaborated and issued by the TO (Art. 6).

Regarding the requirements for requesting the access permit for basic research, bioprospecting or commercial use, the applicant or his representative shall comply with the applicable requirements. Forms are available in the TO and the documents listed in Art. 9 of Executive Decree 31514-MINAE must be attached depending on the type of request. If the interested party presents a private material transfer agreement, as defined by Art. 6 of Executive Decree 31514-MINAE and in accordance with the stipulations of Art. 22 of this regulation, such agreement shall correspond insofar as possible to the agreement template that has been included in Annex I of this Executive Decree.

The prior informed consent and mutually agreed terms must be obtained and negotiated with the owners, managers or representatives of materials held in *ex situ* conditions in accordance with the contract template provided by the TO. In cases where the source and origin of the materials accessed from an established collection are determined prior to the entry into force of the decree, the benefits can be shared with the original suppliers of the same.

Since this pertains the access to new systematized collections (Art. 8, Executive Decree) or the access to new accessions of established collections prior to the entry into force of the Executive Decree, the benefits shall be share insofar as possible, with the original suppliers thereof. In this case, the interested party and/or owner, manager or representative of the materials kept in *ex situ* conditions will provide the TO with a document to enable the permit request, a copy of the prior informed consent and the mutually agreed terms entered into with the original supplier of the resources.

At the time of registration and for any type of request, the applicant makes and oath to respect the code of conduct included in Annex II of this this Executive Decree, which will be reviewed periodically by the TO. This commitment will be marked by the TO in the resolution approving the access permit or the in the framework agreement and the interested party must subscribe to the changes arising from the revision of the code of conduct (Art. 7).

Once the Executive Decree is published, the TO will require holders, owners and representatives of new systematized *ex situ* collections established after the publication date of the Executive Decree, to state the origin and/or precedence or the accessed material. Between the mutually agreed terms and the prior informed consent among the owners, proprietors or managers of the new collection and the original suppliers of the genetic and biochemical elements or resources from biodiversity, an agreement must be drafted pertaining to the potential benefits which may be

derived from a latter Access to these genetic and biochemical elements and resources by a third party (Art. 8). The resolution issued by the TO should clearly indicate whether the request was approved or rejected and the technical, social or environmental justifications on which this approval/rejection is based, and the interested party must be notified. In the case of access to genetic and biochemical elements and resources from biodiversity in *ex situ* conditions, the TO will determine the need to issue the corresponding passport (Art. 9).

The provisions of Art. 10 are relevant (export and certificate of legal origin), since they establish that the permit does not exonerate the interested party from compliance with the requirements for the exportation of live material. If export of such materials were needed, the interested party would necessarily have to request a certificate of legal origin, which will be attached to the material at all times. This will be issued in the terms stipulated by Art. 19 of the Rules for Access *in situ* and the TO will have a maximum period of fifteen calendar days to issue it once the request has been presented. The resolutions and access permits *in situ* might require a duplicate copy to be deposited by the interested party at some of the existing *ex situ* collections, taking into consideration the space and resource availability of the collections. The interested party will indicate the origin of the material and will comply with the technical provisions for the deposit which have been set out in the resolution. Subsequent access to the collections may only be conducted for the purposes of basic research (Art. 12).

If a proprietor, owner or manager of an *ex situ* collection decides to abandon, destroy or export a part or the totality of the collection, this shall be notified to the TO, so the collaboration of other agencies can be sought for the maintenance of material of interest from these collections (Art. 57, Biodiversity Law). Likewise, the TO might –of its own volition or at the request of an interested party– coordinate the support of public, private, national or international entities for: initiatives, programs or projects, resource management, technology diffusion, incentives, technical assistance and technical support and training, among other areas, aimed at promoting *ex situ* conservation (Art 15). Also, in accordance with Transient III (Registry of *ex situ* collections), the owners or managers of *ex situ* collections, or its legal representatives, shall have a maximum period of 10 months from the publication of the Executive Decree to register their collections at the TO of the CONAGEBIO according to the established formats.

7. Tracking and monitoring mechanisms used by the Technical Office

In this case study, legal aspects of monitoring schemes used by the TO in their projects were analyzed. This means applying Art. 20 (Rules for Access) regarding "Verification and Control", establishing that in conformity with the terms of the permit granted the TO will execute it when it deems necessary, in coordination with the interested party or the resource supplier. TO officials might conduct inspections on the land or the site were the access is conducted, through unscheduled visits during the valid period of the permit and they will elaborate Minutes of these monitoring visits.

Failure to comply with the agreements and commitments will result in the cancellation of the permit (Art. 27, Rules for Access). In addition, the interested parties (applicants) are obliged to submit reports, the frequency of which shall be determined by the TO in the resolution of the access permit (Art. 13, Rules for Access). Also, it must be kept in mind that access permits are personal, non-transferable and materially limited to authorized elements or resources and can only be used inside the

area or territory which has been expressly defined under the terms of the resolution of the TO (Art. 24).

In summary, in Costa Rica the mechanisms for genetic resource monitoring and tracking which are actually implemented are the following:

i. Periodic reports referred to in resolutions.

ii. Inspections and visits of TO officials to the facilities of the interested parties or to the place where access occurs.

iii. The TO or the contract template for PIC do not provide specific details for the monitoring of suppliers.

iv. Monitoring of the PIC contract is basically done through reports.

v. Resolutions do not necessarily prohibit the transfer of collected samples, extracts, fractions or derivatives thereof. For instance, Resolution R-CM-INBio-03-2006-OT of March 1, 2006 which grants the *in situ* access permit to INBio for the development of the ICBG Project, does not stipulate a prohibition of sample transfer to other destinations without previously obtaining prior informed consent in writing from the suppliers (First provision, Section10); and neither does it stipulate such prohibition in the case of *ex situ* permits granted (Resolution R-CM-INBio-08-2006-OT, May 17, 2007, Frist Provision, Section 7).

vi. There is no specific procedure or unit created by the TO for monitoring. However, patent databases and publications were reviewed, verifying the correct use of genetic resources described according to the authorizations. National legislation establishes the obligation to submit a certificate of legal origin in requests for patent and plant variety rights which involve genetic resources or traditional knowledge of the country; but to date, there are no institutional procedures, such as forms available at offices that grant such rights to allow for this mechanism to be implemented easily.

Upon legal revision of the case study, possible unauthorized uses on the part of users have been detected, which would require a legal procedure that allows defaulters to regularize situations of unauthorized access. In the past, instruments such as Framework Agreements were used to achieve such purpose. Today this constitutes an important gap in Costa Rican Law, which could be resolved by establishing sanction procedures that allow for some kind of conciliation between the TO and the user.

8. Compliance with legal requirements for the implementation of activities of the "International Cooperative Biodiversity Group

The legal requirements of the Biodiversity Law and Rules for Access to obtain permits are quite detailed, but relatively easy to comply before the TO. Since the year 2004, when the legislation actually started being applied, the TO had accumulated almost two years of experience in the respective procedures prior to the presentation of the request for this case study.

In this context, it should be noted that apart from the requirements of the legislation, the main difficulty of the project was being able to anticipate different situations and try to capture all possible potential changes from the start due to the dynamism of research. This in turn, makes the submission and/or negotiation of the relevant documents, such as the PIC and the request for authorization from the TO when applicable.

The three main requirements related to the access permit –the foundation of the collection activity for further research and development of genetic resources– are listed below from a legal standpoint.

8.1 Materials collection

The legal requirements for collecting the materials are directly related to the access permit, because the collection can only be carried out after obtaining it. Likewise, the use of materials found in ex situ collections of INBio, started after obtaining corresponding permit.

8.2 Registration of the interested party

The INBio was previously conducting a registry for the implementation of access activities in its different modalities, namely: basic research, bioprospecting, and commercial use (Art. 8, Rules for Access). This is why no special formalities were needed for such a registry. This constitutes a unique record as set out in the existing Framework Agreement between the INBio and the CONAGEBIO, signed on May 10, 2005 (Art. 74, Biodiversity Law; Art. 21, Rules for Access).

Overall, the following are the most relevant items referred to in the Framework Agreement that may be of interest in the processing of permits pertaining this study:

i. Registration of the interested party: for the purposes of Art. 8 of the Rules for Access, the TO will conduct the registration of INBio as a potential interested party in the access to genetic and biochemical resources one time and upon request, once all the information required in Art. 8 to be registered has been given. Based on this record, the TO will examine INBio with signatures authenticated by a lawyer in procedures related to the access permits and it will issue the corresponding identification card of access to the institution, which will be valid for the procedure of obtaining the PIC of the various projects occurring during the term of the Agreement.

   Through its legal representative, INBio shall inform the TO (in writing) of any change or modification to the original conditions leading to the unique registration (Art. 9, Paragraph 4.a, Rules for Access), delivering a single written formal commitment which it will abide by during every implemented project. It will also notify the TO of the CONAGEBIO immediately if there is a modification to the purposes of the permit, whether it be for prospecting or commercial use, and it will comply with the requirements established for each case. The unique registration referred to in the present clause will be subject to the term of duration of this agreement.

ii. Technical Guide: in view of the fact that the information required by the request form (Art. 9.1, Rules for Access) is essentially the same information that must be submitted as part of the technical guide (Art. 9.2) and, taking into account the existence of the unique registration in conformity with the second clause of this agreement, INBio will submit only the technical guide for each of the projects for which it requests the access permit and it will henceforth dispense the presentation of the request form, excepting paragraphs c) and f), when deemed appropriate and paragraphs g) and h) which contains information not included in the technical guide, and will be attached to the same. All information required in the technical guide will be submitted via computer and it will presented to the TO in print, along with the payment receipt for the administrative fees, procedure payment and other expenses stipulated by the TO in accordance with Art. 17 of Decree 31514- MINAE.

iii. Research passport equivalent instrument**:** the TO will allow INBio officials authorized for collection to carry a copy of the access permit resolution granted instead of a research passport, provided it has been duly stamped by the Executive Direction of the TO.

iv. Modification of access permit: when during the course of a basic research or bioprospecting project with their respective access permits from the TO, the need arises to make changes to the initial collection plan, accessing different genetic or biochemical resources, in the same places and/or places other than those originally planned, the INBio shall give written notice before implementing such changes and submit the new corresponding PIC, because the TO will include this information in the same access file which was originally granted. It will then proceed to issue a new resolution which incorporates the reported changes.

v. Response time for technical office: the TO will notify INBio in no later than 10 calendar days, about any omissions or corrections to the presented information.

8.3 Presentation of the permit request and technical guide

The permit request and the technical guide meet the requirements of Art. 9 of the Rules for Access, considering the provisions of the existing Framework Agreement between the INBio and the CONAGEBIO that facilitates compliance with certain formalities.

Access permission was requested on November 25, 2005, along with the following documents: the technical guide with its attachments; research information (in digital format) supporting prior knowledge about the elements and resources that will be accessed; an abstract in Spanish of articles that support prior knowledge, and an executive summary of the project.

The project description includes the main elements of the technical guide, but it is important to highlight its contents:

i. Information of the interested party.

ii. Information of the researcher in charge of the

project. iii. Information of the counterpart.

iv. Research data, including: personnel authorized for collection; type of permit (basic research); name of the project; specific objectives; description of the scope; elements or resources that will be investigated; taxonomy of known species; number of times that collection will be conducted on site; collection methods; owner of the property (in this case a private estate of INBio and protected areas owned by the State); exact location where the samples will be taken (different conservation areas during the four years); expected duration of research (four years); and total budget.

v. Potential destination of the resources and subsequent destinations (in the country or abroad).

vi. Studies supporting prior knowledge about the elements or resources that will be accessed.

vii. Way in which the research activities will contribute to the conservation of the species or ecosystems.

viii. Copy of the research project.

ix. Schedule.

x. In this particular case study, the following requirements were not applicable: a description of the traditional knowledge, the commercial use of the resources in case there is an occasional or constant economic benefit, and information regarding the economic feasibility of the project for these purposes. The information is presented under oath.

9. Negotiation of prior informed consent

In the period following the submission of the relevant request and technical guide, and after complying with the required clarifications, the prior informed consent was negotiated with different suppliers. In this particular case, during the first year of the project, the collection would be conducted in three conservation areas: *Guanacaste*, *Arenal-Tempisque* and *Tempisque*, all of them part of the National System of Conservation Areas.

The PIC is negotiated with the directors of the areas and their content is reflected in a contract or binding agreement for the parties involved, in this case the INBio and Conservation Areas. Also, the Director of the National System of Conservation Areas is involved, in its capacity as legal representative. PIC contracts were signed on January 23, 2006 and were submitted for appropriate validation on February 9 of the same year. The PIC contract for this research contained some areas of interest. The most important, particularly in legal terms, are the following:

i. A description of the suppliers.

ii. A description of the authorized access location, exclusively in protected wildlife areas declared as such by the State and belonging to National Natural Heritage, whose administration corresponds to SINAC and where the three areas of conservation suppliers are located.

The PIC negotiated with additional areas, states that collection is allowed in protected areas which are 100% state owned or in state land located within protected areas of mixed ownership. It is therefore authorized, and consent is given for collection in the aforementioned situation while access to private property or land within protected areas of mixed ownership is denied.

iii. The project for which the collection of resources is authorized, which in this case is the Project “Discovery of natural product-based drugs from the Costa Rican biota”.

iv. The purpose of the project.

v. The authorization to enter and the identification of researchers authorized to enter, requires researchers to carry a legible copy of the access resolution granted for the project. Access will be allowed only after coordination and consultation with the research coordinators of the respective conservation areas, and the visit will be coordinated with at least 15 calendar days in advance. Authorized people must carry with them a work log for every conservation area, which will detail the quantity of samples obtained for each: type; collection site; protected wildlife area, and conservation area; as well as the entry and exit date from each visited site.

The log must be foliated, stamped and signed by research coordinators of the areas or someone designated by them to do so; and must also have the signature of the person authorized to access, who will be responsible for directing the field operations. Registration is cumulative for each: conservation area, protected wildlife area, collection site, collection visit, and samples obtained.

vi. The respective term for collection activities defines the access sites and geographic locations within protected wildlife areas. The collection sites are previously defined, by way of an agreement between the interested party and the research coordinators. The parties may define several collection sites within a protected wildlife area for each particular entry. At the end of each entry, the person supplies a list of collection sites visited, presenting the following basic information: the name of the collection site, whether it has one or one has been assigned to it in agreement with the corresponding research coordinator; the coordinates (lambert or satellite); the elevation in meters above sea level, and brief description of the collection site. The maximum number of allowed entries during the term of the contract were set and so the first PIC was for 12 months.

vii. The biological material to be collected is extracted with the authorization of the suppliers, because it consists of the types of samples previously described. In the case of this project, this included: tissues of plants that host microorganisms; selected plants (samples of vegetative organs, leaves and roots), lichens, invertebrates (samples of sponges, tunicates and octopodes, in some cases complete specimens), environmental samples (marine and terrestrial sediment), soil, mud, litter, different types of organic decaying matter, cyanobacteria, and surface water. The PIC negotiated and signed with the various conservation areas contained some variations with respect to the materials to be collected.

During each visit to protected wildlife areas, the interested party must inform research coordinators in advance, notifying them about what specific types of samples will be collected and sites to be visited.

viii. The methods used for the collection of the different samples.

ix. The destination of the resources, which in this case is the INBio and the Centre for Research in Marine Sciences and Limnology of the University of Costa Rica, is authorized by the providers. Abroad, the facilities belong to the University of Michigan; the Harvard University (Broad Institute); the Massachusetts Institute of Technology; the “Field Museum”; the Novartis Institutes for Biomedical Research (to be defined); the Technical University of Braunschweig; the Dana Farber Cancer Institute, and the Howard Hughes Medical Institute.

The prerequisite for sending biodiversity resources outside Costa Rica, are defined when the interested party agrees to negotiate and finalize the terms with the suppliers in advance and in writing with an addendum to the contract. Subsequently, the negotiated PIC with the addendum must be submitted to the TO for processing, clarifying that the interested party may not transfer the original material or duplicate thereof to third parties without prior written permission from suppliers.

x. The Exchange of knowledge and information occurs three months after the expiration date of the contract, when the interested party submits a report in Spanish which contains the partial results of the Project and, eventually, it also occurs in exchanges in person. Likewise, due credits must be given in the case of publications, reports or any other type of presentations.

Suppliers do not authorize further use of the results of the project or of the basic research in bioprospecting or commercial use projects without their prior informed consent.

xi. The transfer of technology or information occurs when the interested party commits to present the knowledge of the researched biodiversity as well as its discovered potential uses to the suppliers, to promote its valorization. Also, the interested party shall provide the suppliers with copies of the publications made as a result of the project.

xii. Benefit sharing applies in the case the activities of the project generate information with some sort of commercial value for the interested party or a third party, or in case of any subsequent licensing and/or the latter generation of any type of marketable product by the INBio or a third party, whether it is in the national or international market. Additionally, if such a license or product represented some sort of economic or material benefit for the interested party, and it was developed on the basis of the information derived from the biodiversity resources collected in protected wildlife conservation areas, the interested party shall pay the suppliers a total of 50% of all the royalties and similar commercial benefits that may hereafter be perceived. The corresponding amount will be deposited in the National Parks Fund as it comes in.

The PIC signed in 2007 is more descriptive when dealing with this issue and it considers potential commercial earnings at a national and international level in the area of obtaining environmental, social, economic, spiritual or scientific benefits derived from the use of the biodiversity resources collected under the terms of the contract, and including not only the original materials which were the reason for access, but also the products or by-products eventually derived from them. This is why the interested party and any third party involved commit to share the exchange of information, the technology transfer, the training and other monetary or non-monetary benefits with the suppliers. All these benefits and others that may not be contemplated must be shared by the suppliers and the original interested party or eventual third parties. The benefit sharing shall be fair and equitable after legally formalizing the *addendum* to the contract.

xiii. The proof of origin, which means committing to register the origin of the products or resources generated from biodiversity, whether it is through a publication, a formality or an assigned later use.

xiv. Considering the dynamism of research due to its scientific nature and its specificities, both parties recognize the possibility to modify the clauses of the prior informed consent validated by the TO (March 28, 2006), especially those related to the sites of access, the types of samples, the authorized personnel and the term of access. Thus, any modification to the PIC shall be negotiated promptly and in good faith.

10. Conditions of the permit granted to access genetic resources at the National Biodiversity Institute of Costa Rica

The TO issued Resolution R-CM-INBio-03-2006-OT on March 1, 2006; thus approving INBio's request for access for basic research entitled: "Discovery of natural product-based drugs from the Costa Rican biota". The permit granted contains the following points of interest:

i. Describe the biological material in a manner consistent with the provisions of the CFP.

ii. Describe authorized scientific method used for collection, and inform the research coordinators of the respective conservation areas about the specific types of instruments used for sampling.

Samples of plants and lichens will go through a preliminary taxonomic study, and every sample of a host species and/or lichen shall have a herbarium specimen deposited in the respective collections for future references. Of all specimens collected, fungi and bacteria will be isolated and subcultured to extract chemical compounds. For this purpose, fractions of some extracts shall be used for anti-cancer, anti-neurodegenerative, central nervous system disorder and anti-parasitarian trials.

All culturable microorganisms were preserved with conventional methods and samples will be kept in the corresponding collections. Also, DNA extractions from the environmental samples will be carried out.

iii. Describe the wildlife areas where access can be conducted and the property of INBio, in accordance with the respective PIC and the obligations pertaining to the sites of recollection.

iv. Communicate promptly to the TO if there are changes in the type of access permit (bioprospecting or commercial use), and meet the requirements for the new permit.

v. Allow TO officials or CONAGEBIO members entry to the places were research is being conducted, to fulfilling their work of verification, monitoring and control (Art. 20, Rules for Access).

vi. Detail the procedure for the entry of collectors to the different areas after previously agreeing about this with the research coordinators.

vii. Subsequent use of the results of basic research in projects with a commercial purpose or for economic gain is not authorized without the prior informed consent of the suppliers. This reaffirms the benefit sharing assumptions established in the PIC contract.

viii. Submit copies of the final results and any articles and publications –once the research project has concluded– to the TO and the conservation areas, providing a summary in Spanish if the text is in another language.

ix. Leave a proof of origin of the products or resources generated form biodiversity through a publication, a formality or later use assigned. Likewise, present the information that allows for the increase the knowledge in all researched areas as well as the potential uses that might be discovered, while achieving the objective of promoting valorization and conservation, and sending copies of the reports to the TO whenever it is required.

x. Determine potential destinations described in the PIC.

xi. Use permit in the territory indicated, since it is personal, not transferable and limited to the authorized genetic and biochemical elements and resources.

xii. In compliance with Art. 74 (Biodiversity Law) and Art. 22 (Rules for Access), present to the TO the conventions or agreements for material transfer defined with the institutions participating in the research project. INBio shall not transfer the original material or its duplicates to third parties without prior authorization from the TO and the suppliers. It is worth clarifying that if the transfer convention or agreement is not presented to the TO, the respective permit will be cancelled. This is why these agreements must be submitted promptly and in Spanish.

xiii. Identify the people whose access is authorized.

xiv. The TO reserves its right to cancel the permit with no consequence whatsoever when any failure to comply with the requirements is proven, whether it is on the grounds of Art. 27 of the General Rules of the resolution, or whether it is on the grounds of any other applicable rule of law.

xv. The term of the permit is 12 months from the date of notification.

10.1 Scope of the collection permit granted at INBio

Since another permit was required, a separate one was obtained for access to genetic resources kept in *ex situ* conditions in the facilities of INBio (Resolution R-CM-INBio-08-2006-OT, May 17, 2006). The legal terms of the permit applied to the *ex situ* case are similar to those described since year 2005 (Table 2), taking into account that there is no PIC contract since the resource supplier is the INBio itself and it must describe the materials to be accessed.

The existing contract between INBio, Harvard University and University of Michigan, is validated (authorized) by means of Resolution CM-AUT-INBio-03-2006-OT-CONAGEBIO dated October 30, 2006 (Art. 74, Law Biodiversity, Section 22, Rules for Access).

A year later, Resolution R-CM-INBio-27-2007-OT dated April 11, 2007 granted a new license to access materials from INBio's ex situ collections (samples of isolate microorganisms identified by a code) , which was issued in similar terms to the previously mentioned resolution and had a term of two years and six months.

Finally, since the original permit was granted for 12 months in Resolution R-CM-INBio-30-2007-OT dated May 25, 2007, a new access was approved after completing nearly the same formalities which have already been explained and described. Modifications included the addition of: new sample types and quantities; the number of entries authorized for each area; the collection sites, and the authorized personnel. Also, unlike the resolution in 2006, this resolution established the prohibition of transfer to other sites without an *addendum,* the formality before the TO; and the PIC contract was negotiated with nine conservation areas, for a term of two years and seven months until de end of the research project.

Table 2. Chronology of the principal legal milestones of the Project "Discovery of natural product-based drugs from the Costa Rican biota".

November 25, 2005	Request and the technical guide of the project are presented
February 9, 2006	PIC contract negotiated with three conservation areas is presented dated January 23, 2006
February 28, 2006	PIC contract is validated at Technical Office
March 1, 2006	Resolution R-CM-INBio-03-2006-OT approves access permit
May 17, 2006	Resolution R-CM-INBio-08-2006 OT approves access permit to *ex situ* materials
October 30, 2006	Resolution Aut-CM-INBio-03-2006-OT authorizes the contract between INBio, the Harvard University and the University of Michigan
February 22, 2007	Request and the technical guide of the project are presented again because previous permit had a duration of one year and was about to expire
May 22, 2007	PIC contract signed by INBio and the nine conservation areas (including the Director of SINAC) is presented
May 24, 2007	Technical Office validates PIC contract
April 11, 2007	Resolution R-CM-INBio-27-2007-OT approves access permit to *ex situ* materials
May 25, 2007	Resolution R-CM-INBio-30-2007-OT approves access permit

11. Contractual agreements and fair benefit sharing

INBio's strategic alliances with two partners, Harvard University and the University of Michigan, were established through an agreement for scientific collaboration. The planning phase of the project is done by defining the work plan in a joint effort among researchers from the parties involved. It is noteworthy that, in most cases, the exchange of technical information to finalize the work plan precedes the signing of a confidentiality agreement, known as CDA, which aims to protect the rights of the parties in the preliminary stages of discussion and exchange of information, aimed at making this collaboration a reality.

The contracts regulate in detail, among others, the following areas of interest: the purpose of the agreement; definitions (includes some core issues such as confidentiality); the scope of work; the funds available; people responsible (research and management); the patenting and licensing of inventions; fair benefit sharing; material transfer (from the point of view of compliance with sanitary and custom regulations mainly) termination; publications; reports; copyright; liability; resolution of controversies; clauses that survive the termination of the agreement; specific clauses derived from federal funding from the United States of America. Annex II: Work Plan which details the responsibilities of each of the three parties involved, as well as joint responsibilities.

The Convention proved to be somewhat more complex in its content, since ICBG's own requirements were incorporated. These requirements were related to the use of federal funds and the possible involvement of a third party (an industrial partner: the NovartisInstitute of Biomedical Research) whose participation is expected by a specific contractual arrangement. Finally, this industrial partner did not join the project and, in its place, two agreements with ESI and Otsaka (commercial partners) were negotiated.

In this scenario, two types of contractual arrangements and their corresponding mechanisms for fair benefit sharing were elaborated: one being a consortium for scientific research amongst the Harvard University, the University of Michigan and INBio, , and another concerning the collaboration agreements signed separately by Harvard University, on behalf of the consortium, with companies ESI and Otsaka. Moreover, in the case of the second ICBG led by the University of Michigan, a different approach was established because any contract with a third party was signed amongst the third party and INBio, the University of Michigan and the Harvard University.

The following are some of the benefits stipulated in the contract of the consortium comprised of INBio, Harvard University and the University of Michigan:

i. Funding INBio's research budget including items such as salaries, equipment and supplies, among others, receiving around US$ 400,000 per year during the term of ICBG.

ii. Agreeing on licensing of inventions and patent clauses, upon written notification of any of the parties regarding any invention generated during the collaboration. The ownership of the patent is established according to the law applicable in the United States and Costa Rica, as well as in accordance with existing contractual and labor agreements of each institution.

The contract stipulates cases of: joint patents, responsibility of each party to file their own patent applications, and rights of the other parties to request a patent if the inventor declines to initiate or continue such proceedings, among other things.

iii. Perceiving the potential monetary benefits derived from the licensing of patents, and other intellectual property or fractions, while respecting the agreement which presents two scenarios with different percentages depending on the origin and ownership of the invention or a licensed fraction.

It is necessary to clarify that in any situation, INBio is entitled to the same percentage, or an even larger one where it is the sole owner of the patent or intellectual property right. The percentages are confidential, as are the costs of requests, even when they are shared and there is a monetary limit for the case of INBio.

iv. Organizing joint workshops every year, particularly on topics such as bioinformatics, designing topics for the benefit of conservation areas and other interested parties if such were the case.

v. Conducting scientist exchanges amongst institutions.

vi. Collaboration between Harvard and Michigan in the development of future research and marketing opportunities.

vii. Making contacts with recognized organizations in the research and development of products.

11.1 Contractual negotiation between the scientific consortium and the business associates

The contracts with the two companies differ, although in both cases an Annex referred to as "Benefits to the host country" (in English "host country") was negotiated and some additional benefits for INBio and Costa Rica were established.

In this legal context, the companies made agreements that established the percentage of benefits or payments, which would be shared between the three institutions participating in the consortium under the provisions of the Collaboration Agreement. The following are some of the Additional benefits:

i. Training at the laboratories of the companies.

ii. Identification of a possible equipment to be donated to INBio or to suppliers of genetic resources, such as the conservation areas.

iii. Funding of a short course or workshop per year.

iv. Funding for printing or purchase of educational materials related to biodiversity, with the aim of distributing it in schools in rural areas or conservation areas.

v. Special consideration should be given in the case of producing pharmaceuticals since they would have special prices or conditions for distribution in Costa Rica.

12. Monitoring arrangements

Tracking and monitoring of samples and research results are related to the following clauses which are applicable to the project:

i. Definitions: in order to ensure that certain clauses of fair benefit sharing and related reports are sufficiently comprehensive, it is necessary to have a wide range of definitions. In addition, one must consider possible transformations of genetic resources by the processes of research and development, including the following: analog, chemical entity, derivative, extract, field of use, fraction, isolation, materials, products, results, samples and trials.

   The definitions require identification using a bar code, applied to original items, such as extracts, and elements derived from the modification made by the partners in fulfillment of their research activities. For example, fractioning and biological activity tests, among others. They also make it possible to have a precise idea of the different transformations of genetic resources undertaken by the different participants.

   When it comes to the definition of an important product which includes all the possible results that may derive from a biological sample, perceiving the monetary benefits in its field of application would apply.

ii. ID or barcode: for each shipment of pre-fractions or extracts should barcode have a unique identifier to ensure traceability of the samples. The partners at Harvard and Michigan shall assign one that corresponds to the INBio and to the results obtained during the study of the extracts.

iii. Patent Application: for every request in must be indicated to Costa Rica which is the origin of the materials used in the required invention.

iv. Use of materials: it is applicable for the project that a transfer to third parties must be previously authorized in writing, detailing the conditions for participation in Annex III of the agreement.

v. Reports: each party must submit periodic reports on the results of the research. For instance, Harvard must provide INBio a list of what is received and associated with their identification number.

Throughout the entire packing list, the information regarding the materials transferred between the parties –whether internally or between them and the companies– will be attached. Thus, in each case the Appendix 1 of the General Provisions of the Contract shall include a detailed description of the material and its related information.

vi. Return materials upon termination of the agreement: when the contract ends the materials must be returned or destroyed at INBio, omitting this process when the material is needed to produce inventions or supporting publications.

vii. Audits and access to research logs: though not contemplated for this project, for others INBio has applied certain provisions which –under certain conditions– allow access to the research logs and allow audits to be conducted by third parties regarding some financial aspects (for instance, the amount of net income to calculate royalties), but are applicable to other spheres of collaboration.

INBio has developed technical, scientific and legal capacities for tracking and monitoring of projects, specifically for analyzing: reports resulting from the research process, databases, and patent applications that list Costa Rica as the country of origin of the resources used in the invention.

In this context, INBio has legal and negotiation capacity to interpret the terms of monitoring applying its legal capacity in the event of discrepancies with partners regarding the scope of such discrepancies or defaults. Typically, research reports, conference calls and visits are made by the scientific staff in charge of the project and possibly other officials who have sufficient knowledge to observe laboratories or access logs and determine the level of compliance with the obligations of the contract, particularly with regard to the tracking of samples.

The database and barcode system are used to track the subsequent use of the materials, but its purpose is to associate them with the information necessary to facilitate the development of research activities and additional supply. In this sense, achieving adequate traceability of the samples and their future direct or indirect use in the development of a product requires, in principle, an ordered collection process , which involves the recruitment of staff trained to collect, sort and manage a database for each sample entering the INBio.

The sample management process involves a cost to the Bioprospecting SAU and is one of the most important in terms of generating added value to biodiversity, because it includes professionals trained in placement, identification and processing of their items, especially in assigning the first bar codes to the samples. Likewise, a computer systems analyst is required to develop particular

databases according to the needs of each project, and to be responsible for distinguishing extracts, isolates and fractions, among others, for their submission to the HTS. Also, the computer analyst is responsible for issuing the required reports for restocking of supplies or the analysis of data when the collaborator has results from the screening of biological activity.

The traceability of materials coming from the laboratories of INBio is a costly activity, which is required for this project and it is calculated to be very high considering audits and verification visits to the institutions in the consortium. Also, this takes time, travel costs and per diem expenses, costs which are typically not considered in research budgets and it is difficult to include them.

12.1 Legal tracking and monitoring mechanisms used by INBio

Generally and independently from the project, the legal mechanisms used by INBio in terms of tracking and monitoring, both samples and genetic resources, can be summarized as follows:

i. The materials out of the laboratories of the Bioprospecting SAU are identified and have a barcode.

ii. Samples transferred to third parties under a partnership agreement or MTA receive a barcode or "simple screening code" which is different from the one used upon entering the Bioprospecting SAU. The partner receives the sample with the full information.

iii. The partner can use its own code to identify the results of the research involving the materials provided by INBio, but it must be ensured that it contains the initial correlation.

iv. The requested restocking usually shows the bar code of both INBio and the partner.

v. The time and the amount of access is limited since it depends on an MTA or a contract. In the latter case, an Annex must be attached which contemplates materials and information transfer as it is conducted.

vi. The receiver can only transfer to a third party with prior written permission of INBio, unless shipments are authorized from the start due to the nature of the partnership. In the case of a MTA, transfer must be accompanied by the legend: "This material has been received through a Material Transfer Agreement, which includes terms and conditions for its use by Third Parties".

vii. The partner is bound by the contract to maintain records and submit reports, including test results and intellectual property right requests, among others, with the purpose of tracking materials and follow up on research results.

viii. The partner is required to allow the INBio, if is so requests to audit and inspect the databases and reports, under certain conditions. In this case study these mechanisms were not used.

ix. INBio can access the research logs related to the materials provided and the work undertaken by the partner. The contract of the current case study omitted this.

x. The bar code could be linked with the permit, which was referred to in the database with its corresponding number. The resolutions are not found in a digitized database, but kept in manual files.

13. Benefits, project results and intellectual property

Overall, regarding the benefits actually received, in terms of research results and a request for intellectual property rights, the following benefits can be pointed out:

i. Full funding for the research for four years.

ii. Conducting workshops on various topics of interest, inviting participants from the various conservation areas involved in the project and other relevant actors. Thus, the knowledge of key aspects in biodiversity research was enhanced.

iii. Training for INBio scientists in laboratories of universities and companies in the consortium.

iv. Subsidy for purchase and distribution of books and other materials related to Costa Rican biodiversity for rural schools and other stakeholders.

v. Conducting short courses and workshops for the benefit of conservation areas and the national conservationist and scientific community.

vi. Interaction with senior scientists, using new techniques and technologies of interest for the achievement of project objectives.

vii. Generation of knowledge and skills for negotiating agreements involving multiple parties (consortium), as well as arrangements with third parties (companies).

viii. A scientific publication with INBio officials as a result of research.

ix. Information generated from the compounds that formed the basis for the development of other contractual relationships, allowing the INBio to continue with the process of finding natural products of interest.

x. To date, the request for copyright related with the results of the research has not been filed.

xi. No product commercialization has been carried out because it takes 10 to 15 years to introduce a medicinal drug into the market.

14. Lessons learned

The following are among the main lessons learned, particularly regarding de legal complexities and difficulties found in the project:

i. The negotiation of the project is complex since it involves three entities and it has restrictions derived from the use of federal funds, which requires the contract to include some clauses which are unusual for these agreements, but which respond to legislation requirements in the United States regarding anti-corruption, anti-terrorism and public health, among others. In addition, each university had to review the compatibility of the contract with their own institutional policies and regulations.

ii. Most negotiations are conducted via electronic exchanges, where once the relation has been somewhat delineated in technical, scientific and economic terms, an initial draft can be elaborated in accordance to what was discussed by the parties involved. Once a more advanced document has been drafted, conference calls are made to agree on some of the important and/or controversial points; this process takes time because it responds to bureaucratic procedures at universities.

iii. The issue of tracking was questioned at one point, especially due to the obligation of disclosure regarding the origin of the materials (Costa Rica) in IPR requests and for considering it included in the usual requirements when a request must be submitted to obtain these.

iv. The legal requirements established in the Biodiversity Law and the Rules for Access for obtaining access permits are relatively easy to fulfill, especially with the TO. In fact, the main difficulty is to anticipate the different situations arising from the development of the project, which might require submitting and/or negotiating documents such as the PIC and the authorization request to the TO if applicable.

The main drawback of procedures lies in the response times of conservation areas for negotiation and signing of the PIC, especially when it comes to projects of collection in different parts of the country, where you must obtain the consent of the Directors of the state protected area you intend to access.

Conservation areas have developed more experience in the negotiation process of the PIC, which has increased their demands, thus requiring more time for the process even when there are existing contract templates.

v. The description of activities is detailed because the Technical Guide and the PIC contract are presented, even including explanatory notes on certain aspects considered of little relevance. Similarly, all official documentation affects collection and other tasks, such as sending samples to certain destinations, since it is difficult to define technical and scientific elements for the project, from beginning to end.

Should changes be verified, the negotiation of an *addendum* to the PIC is required as well as the corresponding permit issued by the TO. Thus, a clause related to the “dynamism of research” must be established which has a certain term at least in PIC for projects, and which allows for a good faith negotiation of later changes to the terms and includes the need to report these changes via a simple note or letter and receiving a response through the same means, while maintaining the conditions of fair benefit sharing and avoiding the modification of the contract.

vi. The limitations contained in the PIC regarding transfer destinations not included under the contract, and which require the written authorization of suppliers (in principle, all destinations), could imply a certain time and effort required to carry out testing elsewhere or transfer samples for other purposes. The same restriction applies to research results, bioprospecting or commercial use without the consent of all of the suppliers.

vii. Contract clauses aimed at providing mechanisms for tracking and monitoring have found no significant opposition among commercial and academic partners, with the exception being cases involving the disclosure of the origin of the materials in intellectual property right requests.

viii. The practical difficulties in monitoring the subsequent transfers to third parties is they must have an ID, and require the written consent of the resources supplier, which in this case is INBio.

ix. Cases like microorganisms have less relevant monitoring and tracking provisions, this is due to the ability of a counterparty to reproduce them entirely.

x. The audits of the contracts have never been used, because visits have been conducted for purposes of coordination and training, among others, as well as to monitor compliance with obligations, but without any specific protocols.

xi. The cost of access to justice in cases of non-compliance can be a barrier, considering the need to have specialized legal advice from abroad. On one occasion, an illegal transfer was detected in another project, a notification of the situation and the existence of an agreement between INBio and a supplier with regulates transfers to third parties was enough to get the samples back.

The case cited above confirms the importance of a clear contract, since the scope of obligations and restrictions to transfer samples and information to third parties was respected.

xii. The application of Art. 15 and 18 of the Nagoya Protocol would address some concerns, by developing appropriate mechanisms for control or verification as well as measures to facilitate the access to justice in cases of non-compliance. It is clear that even with the inclusion of clauses in well written agreements and despite having the institutional capacity for tracking, the cost of litigation in non-compliance cases would hinder the safeguarding of the rights of INBio and the country.

xiii. The issues of contract negotiation and determining changes of use are critical to establishing successful ABS relationships. The first aspect is identified in Art. 22.4.b of the Nagoya Protocol, being mentioned as a weakness for developing countries and indigenous and local communities. The second is in Art. 6.3 (Paragraph g iii) and Art. 8 (Paragraph a) which recognize the importance of regulating.

INBio's experience in negotiating agreements, tracking and monitoring may be of interest in order to tackle the two legal challenges.

15. Websites

International Cooperative Biodiversity Group. 2013. **Program and principles.** Online at: <http://www. icbg.org/program/> Last viewed: January 20, 2013.

Comisión Nacional para la Gestión de la Biodiversidad. 2013. **Presentación del Protocolo de Nagoya y su relación con la legislación costarricense.** Online at: <http://www.conagebio.go.cr/> Last viewed: January 21, 2013.

Case Study in Cuba

© *Rhopalurus junceus* , Dr. Luis de Armas Chavianc

Jorge Cabrera
Medaglia

The venom of the "red scorpion" and other products derived from plant diversity

1. Introduction

This case study was selected in order to document the Cuban experience in research, development and commercialization of biodiversity by-products, such as genetic resources. It is important to highlight all the scientific process of the project was carried out in the country, with the participation of three reputable entities, namely: the Drug Research and Development Center, the Center of Pharmaceutical Chemistry and the Institute of Ecology and Systematic (IES).

In practice, two important factors were taken into account when choosing the research cases that make up the case study in Cuba. The first, was that the biodiversity by-products were commercialized and generated monetary benefits. The second, was that research and development activities were conducted by Cuban institutions, without the intervention of international counterparts (academic o commercial).

Usually, a large majority of ABS relationships rarely end with a concrete good in the market and the benefits obtained are primarily non-monetary, like training and technology transfer, among others. This time, the results were the subject of two patents, demonstrating the importance of counting on institutions to generate added value for genetic resources and to build capacities.

Within this legal scenario, it would be important to clarify the interaction within an ABS framework that exists in the country, in order to improve its implementation with a greater awareness from all stakeholders regarding the provisions of the CBD and the Nagoya Protocol, and also to prioritize the channeling of benefits towards conservation and biodiversity.

2. Biological resources and their by-products

This study researched and accessed biological resources and biochemical components of three different flora and fauna origins or sources: *mango*, venom of the "red scorpion" and *salvia* phytoestrogen.

The three cases are focused on generating biotechnology development, such as scientific research and products based on the biodiversity and genetic wealth in Cuba. Additionally, it is considered important to emphasize that all processes to obtain information about value and marketable benefits were conducted by Cuban institutions of various sorts.

Cabrera Medaglia, J. 2013. The venom of the "red scorpion" and other products derived from plant diversity. In: Rios, M. and A. Mora (Eds.). 2013. **Six Case Studies in Latin America and the Caribbean: Access to Genetic Resources and Benefit Sharing. IUCN-UNEP/GEF-ABS-LAC.** Quito, Ecuador. Pp. 65-75

2.1 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.

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. ii. 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. iii. Patent:
Request No.: 1998/2003.
Number: CU22846N1
Name: pharmacological and nutritional compositions from the extract of *Mangifera L*.
Owner: LABIOFAM.

2.2 Venom of the "red scorpion"

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.

With regards to the level of marketing, raw material from "red scorpion" venom was used for the elaboration of different homeopathic formulas in the industry. 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: Medical Drug Research and Development Center

2.3 Phytoestrogen X

The research started from the basis of popular knowledge associated to the properties of the beach *salvia*, from which a fluid extract with antioxidant properties was developed. Similarly, it should be noted that five scientific articles written by Cuban researchers and related bioprospecting were published.

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

i. Name of the bioproduct: Phytoestrogen

X. ii. Biological resource properties:
Scientific name: *Pluchea carolinensis* (Jacq.) G. Don.
Family: *Asteraceae*.
Popular name: *salvia*.
Resource used: leaf.
Distribution: national.
Availability: cultivated plant.
Plant formation habitat: shrub.
Prospection type: chemical.
Finished product presentations: fluid extract.
Pharmacological action: antioxidant
Level of market penetration: laboratory

trials. iii. No patents have been reported for
this product.

2.4 Actual or potential use of three by-products of biological resources

The existence of scientific institutions in Cuba that make it possible to add value to biological resources and having sufficient endogenous capacity to introduce bioproducts into the market has become an example of how to attain national capacities to demonstrate the value of these genetic resources in responding to actual needs, such as health.

The three examples discussed in this case study illustrate clearly how the resources of flora and fauna, coupled with traditional knowledge, can be converted by in bioproducts with great potential with the intervention of high-level scientific research (Table 1). In short, having the ability to transform raw materials of biological origin (such as *mango*) into products that offer some benefit to the national population, represents a tangible contribution to development.

Table 1. Three products derived from Cuban flora and fauna.

Bioproduct	Resource	Real or potential use	Area
Salvantioxi	*Pluchea carolinensis* (Jacq.) G. Don. *salvia*	Menopause, pneumonia, dysphonia, antioxidant, analgesic, antipyretic, antiasthmatic, neuropathy, hoarseness, and slow digestion.	Health
Vidatox	*Rhopalurus junceus*, Herbst, 1800 "red scorpion"	Analgesic, anti-inflammatory, antitumor, cancer treatment.	Health
Vimang	*Mangifera indica* L. *mango*	Amebiasis, dental analgesic, muscle analgesic, anti-allergic, anti-anemic, anti-carcinogenic, anti-diabetic, antidiarrheal, antispasmodic, ant-stress, anti-genotoxic, anti-inflammatory, contraceptive, mitochondrial antioxidant, anti-proliferative, antiviral, cytoprotective, hepatoprotective, hypoglycemic, humoral immune, immunomodulatory neuroprotective, cell membrane permeability. Treatment of: rheumatoid arthritis, bronchial asthma, arteriosclerosis, prostatic carcinoma, local inflammation and pain, skin diseases, autoimmune diseases, scabies (mange), oxidative stress, hypercholesterolemia, prostatic hyperplasia, skin infections, infertility, immunostimulant, lupus erythematosus, menorrhagia, prostatitis, syphilis, HIV-AIDS. Possible uses to treat various diseases.	Health

3. Main national and foreign stakeholders

In this case study, it is interesting that all research, development and commercial scaling (when applicable) of the bioproducts, were conducted in different Cuban institutions (Table 2). However, it has been difficult to identify whether there were internal contractual agreements or other written mechanisms for the coordination of implemented activities, suggesting that this aspect should be analyzed further.

In the case of Vimang, at some point in the development process, a Belgian counterpart collaborated with a contract that outlined responsibilities, rights and other issues, including intellectual property. The second stakeholders, which were entities that grant collection permits, became involved in the early stages of access and collection of biological materials. It is also said that there were no indigenous peoples or local communities involved in the process.

The three researches are linked to widespread popular knowledge, which is not exclusive of a local group in particular. In this sense, it is stated that: since the 80s, “red scorpion” venom has been said to have an anti-carcinogenic effect; *mango* tree bark was used in local practice, contributing to the development of Vimang; and *salvia* leaves were used nationally, which contributed to the bioproduct process.

Table 2. Cuban institutions that participated in the bioprospecting of the three

bioproducts	
Bioprospecting	Stakeholders – Government Institutions
“Salvia” Phytoestrogen	Institute of Ecology and Systematic; Institute of Endocrinology and Metabolic Diseases, Center of Pharmaceutical Chemistry (CQF).
Vidatox	CQF, Drug Research and Development Center (CIDEM), Entrepreneurial Group of Biopharmaceutical and Chemical Productions (LABIOFAM).
Vimang	CQF, CIDEM and LABIOFAM.

4. Contractual agreements for the development of by-products

Overall, it is possible to identify different types of contractual arrangements in ABS relationships: between the national competent authorities and users; between users and providers of genetic resources or traditional knowledge; and between natural stakeholders and partners or participants of the research, development and eventual commercialization of products, among others.

One of the characteristics of this case study, according to preliminary information available and which must be further analyzed, is that there are no contractual agreements establishing terms of fair benefit sharing. There is also the absence of other arrangements between the authorities responsible for granting access permits (for collecting) and Cuban scientific institutions, and between the latter and foreign entities acting as research, scaling and commercialization counterparts.

With regards to patent licensing, marketing agreements including third party participation in scaling activities or other similar ones have not yet been established. At the moment, the only known instruments are sales and distribution contracts for common products. The agreements for the sale of products contemplate economic benefits as well as other forms of benefits, but these are not seen as usual ABS contracts *per se*.

5. Project and research activities description

Overall, the research and/or collection activities to access to genetic resources are particular procedures, each distinguishable according to the institution used in the development of the corresponding bioproduct.

5.1 Venom of the "red scorpion"

LABIOFAM, the company responsible for research and commercialization of the biological resource, has the corresponding permits to access protected and / or natural areas where resources are located. In this context, a formal access agreement with the Ministry of Science, Technology and Environment of Cuba was never negotiated to determine how to implement Resolution 111 of 1996 which currently establishes the regulatory requirements for research.

The artisanal use of "red scorpion" fluids for medical treatment predates the effective date of the rules listed above. For this reason, even when these regulations were in force when the by-products were registered in the Ministry of Health, an access contract was never formalized despite indications to that effect made by the authorities of the Ministry of Science, Technology and Environment.

5.2 Mango Tree bark

The entity responsible for extracting the *mango* tree bark in cultivated areas is LABIOFAM, in coordination with the Ministry of Agriculture. However, it is unknown if this Ministry has issued permits with the applicable ABS requirements, such as fair benefit sharing of benefits related to Vimang.

5.3 Phytoestrogen from the leaves of beach *salvia*

The scientific research process related to the beach *salvia* and its by-product is underway. Leaves are collected from plants grown in the experimental areas Institute of Ecology and Systematics, the state institution where the bioproduct is developed.

In this research, the information gathered revealed that it is unknown whether the Institute of Ecology and Systematics requested an access permit from the competent national authority: the Ministry of Science, Technology and Environment.

6. Benefits generated and shared to date

Vidatox and Vimang –the marketed bioproducts– are generating positive results in the treatment of conditions proposed by the traditional and / or popular use. They are being marketed nationally and internationally. Currently, specific data on sales levels are still unknown at the national and international levels particularly with respect to: the quantity of the product, use in selected sectors and the monetary income received.

The nature of the bioproducts generates monetary benefits, both from the sale of products, as well as from the availability of new treatments for certain health conditions. In this sense, it is said that apparently there were no contractual agreements with third parties or among Cuban institutions responsible for research and any counterparts, which means there are no other forms of benefits. Lastly, special emphasis should be given to the publications which came as a result of research and the valuable information reported on natural products – especially when these are documents of public dominion and they contribute to the advancement of science.

7. Scope and status of research activities

Currently, two bioproducts stand out which are currently being marketed, and one is in research stage. The scientific studies for the latter are being conducted in the institutions where it initially started, with laboratory and practical trials are advancing and which respond to the management plan related to the potential product.

7.1 Tracking and monitoring mechanisms

The tracking and monitoring mechanisms for the three research topics were not established specifically because the genetic resources never left Cuba for further research and development processes.

The text of the permits omitted specific regulations to monitor the use of biological resources, possibly because it involved Cuban rather than foreign institutions. The end result, except for the case of salvia, was reflected in bioproducts traded in markets without any tracking or monitoring mechanism to ascertain the origin.

7.2 Impact on local socio-economic and / or institutional conditions

The development of bioproducts at institutional level made it possible to demonstrate the scientific capacity of Cuban institutions for market research and negotiation, while positioning products coming from the Cuban biodiversity.

With respect to the local socio-economic conditions, the main impact is the availability of new products and the use of economic resources in actions aimed at the population's well-being, such as health and education, among others. The link or direct mechanism to channel the benefits to specific areas would be determined by the way the Cuban system of social and economic policy operates.

7.3 Intellectual property rights status (IPR)

Decree 290/2012 on the protection of inventions stipulates the requirement for disclosure of the origin of biological material when a patent application is involved (effective as of April 2012), and Decree 291/2012 on the protection of plant varieties establishes the same requirement.

Art. 26, paragraphs J and K of the Patent Law clearly states that the requirements to file a request are: presenting a copy of the prior and explicit authorization of access to biological material issued by the competent authority, particularly when the invention, its parts or its by-products come from genetic resources originated in Cuba or is present in domesticated or cultured species in the country (paragraph J).

When applying the Patent Law to biological material that is linked to an invention but is not obtained in Cuban territory, a statement is required that mentions the country of origin, the source of the biological resource or associated traditional knowledge and the prior informed consent (paragraph K).

Patents for both marketed bioproducts were issued in Cuba, under the name VIDATOX and Vimang. It was later suggested that the scope and content of these documents be one of the topics to be researched due to the following:

i. Patents related to VIDATOX:

   Patent CU 22413, entitled "Antitumor Composition", requested in 1994 and granted in the form of a certificate of Inventorship, will be valid until January 11, 2014. No international requests have yet been submitted.

ii. Patent for the venom of the "red scorpion":

   Request 2010-186 in process, entitled "Peptides from the venom of the *Rhopalurus junceus* scorpion, pharmaceutical composition", published on June 21, 2012. Protection abroad was suggested through the system of the Patent Cooperation Treaty.

iii. Patents related to Vimang:

   Request 1998-203, submitted on December 29, 1998, entitled: "Pharmaceutical and nutritional compositions from extracts of *Mangifera indica* L."; Certificate/Publication No. 22846; granted to the Center of Pharmaceutical Chemistry; ceded to LABIOFAM as Holder of Inventorship Rights, valid until December 29, 2018

7.4 Description of conflicts or agreements reached

The data collected in this case study reveal that no conflict has been found. The only remarkable fact, refers to the Ministry of Science, Technology and Environment when, at one particular point, it asked for a contract for access to be signed, which was never finalized and practically never affected the stakeholders or had any implications for them.

8. Lessons learned

Among the lessons learned, particularly due to the legal complexities and difficulties encountered during the project, the following can be highlighted:

i. Submitting two requests for patents is an indication of the possibilities of generating innovations based on the biodiversity of a country, and under the protection of IPR.

ii. Access activities, such as collection and others, were regulated by the competent national authorities. So it would have been interesting to determine the outcome of applying the ABS regulations with the requirements of the Nagoya Protocol, as they would have produced changes in the conditions of the investigation and fair benefit sharing, among other things.

One possible partial explanation for the Cuban approval process for research projects would lie in a proposal of getting them approved by various Cuban institutions before the start of activities. To some extent it has been suggested that such action would amount to a permit or contract for access, but the approval is not formally issued as such.

iii. In the case of the two bioproducts marketed, popular knowledge was not directly integrated into the considerations for fair benefit sharing, perhaps due to the lack of legal provisions on the subject. In addition, it should be determined whether the profits were channeled to the conservation of biodiversity and local people, excepting the availability of new products for medical treatment, without losing sight of the Cuban model for social and economic policy.

It is important to examine whether there is a legal mechanism for the protection of traditional knowledge, because it would imply changes in the formulation and implementation of research.

iv. Cuban patent legislation of 2012 establishes a mandatory link between ABS and IPR applications, both for the case of the use of Cuban genetic resources (Patent Law, Paragraph J) and foreign ones (Paragraph K). If the legal requirements were applied to patent applications that predate the entry into force of the Law, the way in which inventors fulfill the provisions of the law would be an element of interest in order to illustrate the link between the national ABS system and the new IPR requirements in institutional practice.

v. The two studies that used patented bioproducts employed chemical prospecting aimed at biochemical resources. This reaffirmed the importance of considering access to genetic and biochemical resources within an ABS framework, as it is currently stipulated in the Nagoya Protocol (Art. 2).

Case Study in Ecuador

Gabriel Ricardo Nemogá-Soto
and
Oscar Andrés Lizarazo
Cortés

Global Ocean Sampling Expedition, Galapagos National Park: collection activities and implementation of legislation

1. Introduction

During the course of 2003 and 2004 researches led by J. Craig Venter conducted a "Global Ocean Sampling Expedition", collecting more than 150 samples from 200 liters of sea water every 200 miles. In Ecuador, according to the Memorandum of Understanding (MU) signed between the "Institute for Biological Energy Alternatives" (IBEA) and the State, the following scope was established: "Whereas IBEA is undertaking a global ocean expedition to implement a scientific research project on microbiological diversity in Galápagos with the aim of characterizing it in coastal waters and terrestrial communities around the islands."

The project was presented to its implementers as an activity to raise awareness about microorganisms that inhabit the seas, discovering how they function in their natural systems. This in itself would provide the basis or would allow the possibility to conduct studies on the effects humans have on the environment and understand the evolution of life on Earth.

In the case of Ecuador the signed MU states that "(…) to determine the complex interrelationship between microorganisms groups, especially the ones affecting environmental processes of regional and global importance, a microbial sampling using a "whole environment" genomic approach will be performed with the vessel R.V. Sorcerer II" (MU, Background 3).

Samples were mostly collected in international waters i.e. not subject to national ABS rules, while others were collected in the territory of 17 countries of Central and South America including: Ecuador, Mexico, Panama and Honduras. Additionally samples were collected in: North America (Canada and United Stated of America); Oceania; South Pacific (New Caledonia, French Polynesia and Vanuatu); Africa (Tanzania and Seychelles); Europe and United Kingdom (Sargasso Sea and Bermuda).

2. Biological resources and by-products of the "Global Ocean Sampling Expedition", Galapagos National Park

The MU talks about microbial diversity of microorganisms without specifying quantities or giving a greater level of details. In this sense, this situation is partly explained by the type of resources but there is no further description. There may be eventually more information on the collection permits issued by the Galapagos National Park but at the time of data collection for this case study it was not possible to access this document.

Nemogá-Soto, G.R. and Lizarazo Cortés, O.A. 2013 Global Ocean Sampling Expedition, Galapagos National Park: collection activities and implementation of legislation. In: Rios, M. and Mora, A. (Eds.), **Six case studies in Latin America and the Caribbean: Access to genetic resources and benefit-sharing.** IUCN- UNEP/GEF-ABS-LAC. Quito, Ecuador. Pp. 77-88.

2.1 Actual or potential use of biological resources

In the MU the actual or potential uses of the resources collected are not detailed. It simply mentions in a general and abstract way that the samples on which the project lies are "(…) to determine the complex interrelationship between microorganisms groups affecting environmental processes of regional and global importance (…)".

It is worth mentioning that in 2004 it was already known that marine microorganisms have potential in different processes such as enzymes industries and associated fields and in the biofuel sector.

2.2 Main national and foreign stakeholders

The main stakeholders involved in this research according to the reviewed documents are as follows:

i. MU: signed by IBEA and Ecuador.

ii. National Competent Authority: Ministry of Environment of Ecuador (MAE) subscribes the MU on behalf of the country.

iii. Applicant: IBEA represented by its CEO J. Craig Venter Ph.D., who subscribes the MU as applicant.

iv. Research permit for collection: issued by the Galapagos National Park.

v. Research permit: The Charles Darwin Research Station, an academic and scientific institution recommended the approval of the research "as it is of great value to better understand the role of microorganisms in marine environmental processes".

vi. Technical Advisor: researcher at the University of Guayaquil who submitted a report which partially supports the issuance of the research permit. The document mentions that the proposed research "will promote the scientific, technological and technical capacity at a national level with purposes of conservation of biological diversity and sustainable use of biological resources".

3. International contractual agreements and national stakeholders

The following are the contractual agreements established among the main stakeholders involved in this research in accordance with the documents reviewed:

i. Research permit for collection: issued by the Galapagos National Park.

ii. "Memorandum of Understanding for the Collaboration in Microbial Biodiversity".

iii. Duration of permits and MU, a term of two years was established from the signing on March 15th, 2004, and it may be renewed by mutual agreement of the parties.

iv. Joint Project Plan, if the parties do not develop within one year from the signing of the MU it will terminate without any further obligation.

Clauses 4 (Intellectual Property), 5 (Publication and Dissemination) and 8 (Miscellany) of the MU will survive any termination.

3.1 Detail of benefits included in the agreement

The MU has no specific clause on monetary benefits per se because according to the CBD terminology, it refers to obtaining more "knowledge" on biodiversity than "conservation". In this sense, the situation is materialized in a general and abstract way, without indicators in the fifth clause that establishes:

> "5. Publication and Dissemination of Information.
>
> 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...

4. Results of the "Global Sampling Expedition", Galapagos National Park

The first results of the expedition were broadcasted in 2004, in the prestigious international journal "Science". Other data was published during 2007 in a series of eight articles in a publication of free access called "PLOS Biology", where three of them were classified as scientific (Natarajan *et al.* 2007; Rusch *et al.* 2007; Yooseph *et al.* 2007).

4.1 Benefits generated and shared up until 2012

Not one publication has an Ecuadorian researcher as co-author. In the first research published by the journal "PLOS Biology", among the 34 co-authors we find: 28 residents in the United States of America; 4 assigned to Mexican universities; 1 assigned to research institutions in Costa Rica, and 1 linked to an institution in Chile.

Authorship or co-authorship are not something you get or deserve by way of a fair distribution of benefits; it depends on the effective participation and contribution in a project and on the writing of the manuscript. One of the published documents mentions the Ecuadorian Staff on the acknowledgments, while in others the sovereignty of countries over the samples is recognized, which is a positive and unusual step forward but still not enough. It must be clarified that by the time of the expedition, the Bonn Guidelines 2002 –which are not binding– were known but could nevertheless be considered in the relationship between governments, especially between the Ecuadorian government, and the J. Craig Venter Institute (IJCV).

4.2 Scope and status of activities

The genetic information obtained during the research was made available in two databases known as:

i. Gen Bank, a database managed by the National Institute of Health of the Unites States of America.

ii. CAMERA, a new database for metagenomic information.

The JCVI said that it would not seek patents or other intellectual property rights on genomic DNA and sequenced data. Preliminary searches do not show directly related patent applications. However, since it is mandatory to disclose federal grants (Bayh Dole Act), there are two that cite the same funding from the Department of Energy of the United States of America who co-founded the expedition. When analyzing the documents, it was notified that the funds covered two different JCVI projects: on the one hand the ocean expedition and on the other the study "Reconstruction of a Bacterial Genome from DNA Cassettes".

4.3 Chronology of the expedition led by J. Craig Venter

The main facts related to the case study on the expedition led by J. Craig Venter are listed below:

i. August 2003, presentation of the Global Ocean Sampling Expedition in Halifax, Nova Scotia.

ii. J. Craig Venter and his team collected samples in Mexico on January 9, 2004, fact published by researchers in: "A collection of articles from the J. Craig Venter Institute's Global Ocean Sampling expedition" (PLOS Biology, Special Collection, March 2007, Volume 5, Fascicle 3).

iii. J. Craig Venter collected samples in Honduras on January 10, 2004, fact reported by researchers in: "A collection of articles from the J. Craig Venter Institute's Global Ocean Sampling expedition" (PLOS Biology, Special Collection, March 2007, Volume 5, Fascicle 3).

iv. J. Craig Venter collected samples in Panama between January 12 and 20, 2004, fact reported by researchers in: "A collection of articles from the J. Craig Venter Institute's Global Ocean Sampling expedition" (PLOS Biology, Special Collection, March 2007, Volume 5, Fascicle 3).

v. J. Craig Venter collected samples in Costa Rica between January 21 and 28, 2004, fact reported by researchers in: "A collection of articles from the J. Craig Venter Institute's Global Ocean Sampling expedition" (PLOS Biology, Special Collection, March 2007, Volume 5, Fascicle 3).

vi. J. Craig Venter collected samples in Ecuador between February 1 and March 2, 2004, fact reported by researchers in: "A Collection of Articles from the J. Craig Venter Institute's Global Ocean Sampling Expedition" (PLOS Biology, Special Collection, March 2007, Volume 5, Fascicle 3).

vii. J. Craig Venter collected samples in Galapagos during February 2004, authorizations issued by the Ministry of Foreign Affairs and the Galapagos National Park granting permission to export samples PT 7.5 FR 28".

viii. J. Craig Venter gives a press conference on March 4, 2004 in Washington D.C.

ix. J. Craig Venter and the expedition vessel ship out of Ecuador on March 7, 2004.

x. The MU is signed on March 15, 2004, requesting to formalize the document before allowing him to ship out with the samples.

xi. J. Craig Venter and JCVI request on August 30, 2005 permission to publish the results.

xii. J. Craig Venter receives an answer from MAE on October 25, 2005 specifying that he should:

- Sign a contract to access genetic resources.
- Not pursue intellectual property rights.
- Request authorization from MAE before publishing any data.
- Complete a series of requirements before being granted with any authorization.
- Discontinue using means to stop using the results until an access contract is signed.
- Translate to Spanish: trip reports, laboratory analysis, preliminary interpretations and genetic sequences of samples collected.

xiii. J. Craig Venter and his team members on March 2007 published a collection of eight documents including three scientific research articles in PLOS Biology (Table 1).

5. Models for the dissemination of results

Nowadays, the great potential and sometimes the need for open approaches is recognized in its various forms as well as in its limitations, including what Chander and Sunder (2004) call "The Romance of the Public Domain", i.e. to believe that if a resource is open to all it may be equally exploited, forgetting that in reality the different circumstances of knowledge, infrastructure and power would determine the possibility of profit. It also refers to the Martinez and colleagues topic (2003) in his article "The Geography of the Genome".

Regarding the dissemination of results there are two models. The first, stemming from the interest of protecting intellectual property rights and obtaining patents such as *Diversa*, who operates under the concept of property by patenting what has been achieved in research. The second is a model which promotes the dissemination of information gathered from a wide and free distribution database such as the Venter Institute's case. This last argument is presented as beneficial to mankind but could have a negative impact and prevent the country where the resources originated from benefiting from their potential marketing. Bermuda is an example since

Sargasso has a research program in partnership with

a local station and has invested six years through *Diversa*. In contrast, the Venter Institute published 1.2 million fragments of genes of the same geographical area. The facts do not cease to raise questions for a company such as *Diversa*, since one wonders if it would be willing to maintain its strategy of negotiated access and pay for resources that can now be freely available in a public database.

The context of this legal scenario can be transferred to the J. Craig Venter Institute's proceedings that promised not to patent microorganisms or genetic sequences collected. Nevertheless, it could request patents on modified microorganisms or new artificially designed life from microorganisms obtained by the "ETC Group, Playing God in the Galapagos: J. Craig Venter, Master and Commander of Genomics on Global Expedition to Collect Microbial Diversity for Engineering Life" (Communique 84, March/April 2004, cited in Rimmer 2009).

With regards to the open source model promoted and associated to the project for its benefit to science and humanity, a closer look is required. In practice this system of forthright provision to promote innovation seems to incorporate elements of a non-market and solidarity economy emphasizing open access and promoting participation. Concerning this, Barbrook (1998) and Rullani (2005) consider that, on one hand, software and high technology companies use it to take the additional value produced by the free online collaboration; and on the other hand, that Delfanti and his colleagues think that "free and open access are new models of capitalist exploitation and not just two paradigms of scientific ethics." (Delfanti 2009)

Open source models could be closest to common property regimes of mankind such as the UN Convention on the Law of the Sea. Thus, it would be further away from the proprietary model and national sovereignty established by the CBD that entails a participation of the benefits derived under an owner-based business relying on contracts, patents, trade secrets or other intellectual property rights.

6. Lessons learned

Among the main lessons learned, especially due to the legal difficulties and complexities found in the project, the following can be highlighted:

i. The implementation of a public policy and legislation related to facilitating the access to genetic resources and contracts for scientific research on biodiversity with foreign institutions must balance the specific benefits for the country of origin of the resources, especially for the effective strengthening of their scientific and technological capacities.

ii. Consider the development of a rule to indicate the origin of samples because it is a political, legal and technical issue as it has components in partnership with the "International Nucleotide Sequence Database Collaboration" (INSDC), patent and scientific journal offices.

iii. Create a minimum standard of terms of use for digital genetic information that takes into account the need for a scientific information exchange.

iv. Caution establishing checkpoints, avoiding an overload for nationals in Latin America and the Caribbean.

v. Consider changes on the ways of bioprospecting.

Table 1. Academic articles: authorship by nationality in the research published by the PLOS Biology journal, showing the number of domestic and foreign participants of the expedition. Ecuadorians are mentioned in the acknowledgment but are absent in the co-authorship even when the authorization considered the participation of researchers of the University of Guayaquil.

"The Sorcerer II Global Ocean Sampling Expedition: Northwest Atlantic through Eastern Tropical Pacific"	Total	United States of America	Mexico	Costa Rica	Chile	Ecuador
Number of people who conceived, designed and performed the experiments and wrote the scientific papers.	34	28	4	1	1	0
Acknowledgment		6				Washington Tapia, Director, Galapagos National Park. Charles Darwin Station Staff. Héctor Chauz Campo, Institute of Oceanography of Ecuador. Simón Ricardo Villamar Tigrero, national parks in the Galapagos Islands.

"The Sorcerer II Global Ocean Sampling Expedition: Expanding the Universe of Protein Families"	Total	United States of America	Mexico	Costa Rica	Ecuador	Honduras	Panama
Number of people who collaborated in writing the article	33	33					
Acknowledgment Ecuador, and		4	Governments: Canada; Mexico; Honduras; Costa Rica; Panama; France for French Polynesia, collections authorized in waters of their genetic heritage.				

"Structural and Functional Diversity of the Microbial Genome"	Total	United States of America	Mexico	Costa Rica	Ecuador	Honduras	Panama
Number of people who collaborated in writing the article.	5	5					
Acknowledgment		8	Governments: Bermuda; Canada; Mexico; Honduras; Costa Rica; Panama; Ecuador, and France for French Polynesia, collections authorized in waters of their genetic heritage.				

Source: Natarajan *et al.* 2007; Rusch *et al.* 2007; Yooseph *et al.* 2007.

vi. Correct application of the Bonn Guidelines as they were almost omitted from the project, suggesting an adequate implementation of the Nagoya Protocol.

vii. Raise awareness because microbial diversity presents a greater challenge in the exercise of sovereignty.

viii. Consider a common treatment for microorganisms as well as debates on the idea of common microbiota taking into account its distribution.

ix. Relation to similar projects considering international treaties, in this case the CBD, and the UN Convention on the Law of the Sea (Rimmer 2009, p. 12; p. 158) and the Exclusive Economic Zone.

x. Consider the development of a regional cooperation and unified positions to participate in this kind of projects or similar.

xi. Legal advice to strengthen provisions and disseminate signed contracts publicly (subject to confidentiality). The MU signed with Australia (November 2004) regarding the Sorcerer II Expedition registers a greater content than the one with Ecuador (March 2004), possibly revealing a difference in bargaining power. Rimmer says:

"The agreement is much better than the previous memorandum of understanding established between the Institute and other jurisdictions. The Sorcerer II Expedition has been working with research teams from Australian universities and research institutes" (Rimmer 2009, p. 36; p. 182).

"MUs with countries in Latin America and South Pacific were rather poorly structured. The agreement on Biological Resources established between the Australian Government and the Institute was by far more rigorous on benefit-sharing. The Sorcerer II Expedition reinforces the need of a stronger and harmonized national regime to access genetic resources in Australia" (Rimmer 2009, p. 39; p. 185).

xii. Consider a scheme for results dissemination based on free and open dissemination does not prevent eventual situations of biopiracy because raw data is usually published.

If genetic information is publicly accessible, chances of obtaining its patent are prevented or reduced, even when the issue is more complex, there is a possibility to request patents on modified, processed and combined data; additionally, in some cases business models are built based on charging for related services but not for access to information. In this regard experts say: "Trade secrets, intellectual property rights and services that come from open access to data are three main methods of making money with biological information" (Delfanti *et al.* 2009, P. 423).

xiii. A clarification about obtaining patents is needed because it does not necessarily entails acts of biopiracy if new products and procedures of high inventiveness are obtained and developed from genetic resources and/or from by-products with Prior Informed Consent (PIC) and Mutually Agreed Terms (MAT).

xiv. Establishment of a suitable model for dissemination of results, whether proprietary or open, considering that no scheme is best since each style has potential and limitations, advantages and disadvantages. This is why there must be a thorough understanding of intellectual property and how to articulate it with bio-businesses as its diffusion can play for or against the interests of stakeholders involved.

xv. Consider establishing more expedite and fluid communication channels between Competent National Authorities of each country and other related entities such as the Ministry of Foreign Affairs, National Parks, Intellectual Property Authorities and Universities among others (Thornström 2012). This situation would apply not only when formulating public policies, but also –when necessary– to promptly solving special , complex or "novel" cases or situations while considering all relevant technical and legal elements.

xvi. Documenting the management experiences in research, bioprospecting, and access and benefit-sharing cases. The experience in the Venter Galapagos case could serve so other countries in Latin America properly address the sampling expeditions in marine areas such as the Malaspina led by Spain and Tara Oceans led by France, but available information suggests that it may not always be the case.

xvii. Consider that the "omics" –genomics, proteomics, metagenomics and bioinformatics– could also provide an opportunity in research, knowledge, conservation and sustainable use of biodiversity for Andean and Caribbean countries. In some countries like Colombia, there are research centers working in these areas and building national capacities. The design of rules, public policies and contractual agreements to access genetic resources must anticipate the need for cooperation with foreign research centers in order to strengthen scientific and technological capacities of the countries of origin of resources and other aspects on benefit-sharing

7. Bibliography

Chander, A. y M. Sunder. 2004. The Romance of the Public Domain. **California Law Review 92: 1331-1373.**

Delfanti, A, Y. Castelfranchi y N. Pitrelli. 2009. What Dr. Venter did on his Holidays: Exploration, Hacking, Entrepreneurship in the Narratives of the Sorcerer II Expedition. **New Genetics and Society 28(4): 415-430.**

Helmrich, S. 2007. Blue-Green Capital, Biotechnological Circulation and an Oceanic Imaginary: A Critique of Biopolitical Economy. **BioSocieties 2(3): 287-302.**

Ministerio del Ambiente del Ecuador and The Institute for Biological Energy Alternatives. 2004. ***Memorando de entendimiento para la colaboración en biodiversidad microbiana.*** Ecuador. Quito, Ecuador. 6 pp.

Natarajan, K.; S.S. Taylor; Y. Zhai; J. Craig Venter and G. Manning. 2007. Structural and Functional Diversity of the Microbial Kinome. **PLOS Biology 5(3): 467-478**

Nicholls, H. 2007. Sorcerer II: The Search for Microbial Diversity Roils the Waters. **PLOS Biology 5(3): 380-383.**

Parthasarathy, H.; E. Hill y C. Mac Callum. 2007. Global Ocean Sampling Collection. **PLOS Biology 5(3): 369-370.**

Pottage, A. 2006. Too Much Ownership: Bio-Prospecting in the Age of Synthetic Biology. **BioSocieties 1(2): 137–158.**

Rimmer, M. 2009. The Sorcerer II Expedition: Intellectual Property and Biodiscovery. **Macquarie Journal of International and Comparative Law 6: 147-187.**

Rullani, F. 2005. **The three dimensions of a communitarian institution. The Open Source Software Community Case**. AICCON Working Papers 16. 32 pp.

Rusch, D.B.; A.L. Halpern; G. Sutton; K.B. Heidelberg; S. Williamson; S.Yooseph; D. Wu; J.A. Eisen; J.M. Hoffman; K. Remington; K. Beeson; B. Tran; H. Smith; H. Baden-Tillson; C. Stewart; J. Thorpe; J. Freeman; C. Andrews-Pfannkoch; J.E. Venter; K. Li; S. Kravitz; J.F. Heidelberg; T. Utterback; Y.-H. Rogers; L.I. Falcón; V. Souza; G. Bonilla-Rosso; L.E. Eguiarte; D.M. Karl; S. Sathyendranath; T. Platt; E. Bermingham; V. Gallardo; G. Tamayo-Castillo; M.R. Ferrari; R.L. Strausberg; K. Nealson; R. Friedman; M. Frazier y J. Craig Venter. 2007. The Sorcerer II Global Ocean Sampling expedition: Northwest Atlantic through Eastern Tropical Pacific. **PLOS Biology 5(3) 398-431.**

Yooseph, S.; G. Sutton; D. B. Rusch; A.L. Halpern; S.J. Williamson; K. Remington; J.A. Eisen; K.B. Heidelberg; G. Manning; W. Li; L. Jaroszewski; P. Cieplak; C.S. Miller; H. Li; S.T. Mashiyama; M.P. Joachimiak; C. van Belle; J.-M. Chandonia; D.A. Soergel; Y. Zhai; K. Natarajan; S. Lee; B.J. Raphael; V. Bafna; R. Friedman; S.E. Brenner; A. Godzik; D. Eisenberg; J.E. Dixon; S.S. Taylor; R.L. Strausberg; M. Frazier y J. Craig Venter. 2007. The Sorcerer II Global Ocean Sampling Expedition: Expanding the Universe of Protein Families. **PLOS Biology 5(3): 432-466.**

8. Websites

Barbrook, R. 1998. **Hi-tech gift economy.** First Monday 3 (12). Online at: <http://firstmonday.org/htbin/cgiwrap/bin/ojs/index.php/fm/ article/view/631/552> Last viewed: August 1st, 2013.

El comercio. 22/05/2011. **Expedición científica francesa renuncia a investigar cambio climático en Galápagos.** Online at:<http://www.elcomercio.com/sociedad/Galapagos_0_485351612.html> Last viewed: February 1st, 2013.

Extra. 23/05/2011. **Expedición francesa no obtuvo autorización: no investigarán las Galápagos.** Online at: <http://www.extra.ec/ediciones/2011/05/23/especial/no-investigaran-las-galapagos/> Last viewed: Febuary 1, 2013.

Martínez, R., J. Enríquez y J. West. 2/06/2003. **The Geography of the Genome. Wired**. Online at: <http://www.wired.com/wired/archive/11.06/dna_spc.html> Last viewed: February 1st, 2013.

Parque Nacional Galápagos Ecuador y Ministerio del Ambiente de Ecuador. 2013. **Manual de procedimientos para científicos visitantes en las áreas protegidas de Galápagos.** Online at: <http://www.galapagospark.org/documentos/manual_cientificos_visitantes_galapagos.pdf> Last viewed: February 1st, 2013.

Paz y Miño, C. 2 /10/2011. **Defender los genes (II).** El telégrafo. Online at: <http://www.telegrafo.com.ec/index.php?option=com_zoo&task=item&item_id=17245&Itemid=6> Last viewed:

February 1st, 2013.

Ulloa, G. 24/03/2011. **Islas Galápagos: Científicos franceses sin permiso para investigar sobre el cambio climático.** At: <http://www.biobiochile.cl/2011/05/24/islas-galapagos-cientificos-franceses-sin-permiso-para-investigar-sobre-el-cambio-climatico.html> Last viewed: December 1st, 2012.

Case Study in Panama

© Cyanobacteria in the Portobelo National Park, Kevin

Jorge Cabrera
Medaglia

"International Cooperative Biodiversity Group"

1. Introduction

This case study describes and analyzes the "International Cooperative Biodiversity Group" (ICBG) in Panama selected for its course and results, especially in terms of the non-monetary benefits that this collaborative effort has produced. It is nearly 15 year research of genetic resources of biodiversity mainly financed with international funds.

The initiative generated significant non-monetary benefits that illustrate how bioprospecting can contribute to the development of national capacities in areas mainly related to the conservation and sustainable use of biodiversity resources.

It is important to point out that the ICBG in Panama began before the enactment of the first rules of access issued in 2006 and modified later on in 2009. This allows for the analysis of the potential impacts that may exist on a current ABS scheme, especially for the legal implications that a subsequent implementation has in legal frameworks of national laws and regulations.

2. Operating Models of the "International Cooperative Biodiversity Group"

A better understanding of how the ICBG works in Panama can be reached through the different structures or models that it has in countries or regions where it has been implemented, since it is usually designed and structured following the two big models described below:

i. The first is the "hub and spoke" which means operating under a single agreement involving the main different actors who participate in the prospection, such as: collectors, different research institutes and some pharmaceutical companies. Thus, each one of the parties is directly linked to each other by a single contract or agreement. Consequently, responsibilities and rights are integrated in a single document recognized by all.

   An example of the structure applied by the ICBG is the agreement between the National Biodiversity Institute (INBio) of Costa Rica, Cornell University and Bristol-Mayers. The agreement had some advantages like the transparency and the Part's knowledge about its content and the development of the relationship, but it also had difficulties due to the complex negotiation between the two participants and the management of issues such as intellectual property rights, because its multipart structure presented some regulation challenges.

Cabrera Medaglia, J. 2013. "International Cooperative Biodiversity Group". In: Rios, M. and Mora, A. (Eds.), **Six case studies in Latin America and the Caribbean: Access to genetic resources and benefit-sharing.** IUCN-UNEP/GEF-ABS-LAC. Quito, Ecuador. Pp. 89-103.

ii. The second structure is denominated radial, and it consists of an approach of various contractual relationships between participants but without a single agreement. Therefore, only one of them participates in all contracts or agreements while others are legally excluded for they are not participants and without prejudice of eventually being benefited under the figure of stipulation in favor of a third party referred to in the Civil Code.

Usually in this model there is an agreement between the main researcher of the ICBG and government authorities and this agreement has other contracts with pharmaceutical companies for example or with NGOs, academic institutions and/or research centers among others. Thus, this is the structure that several approved ICBG follow, among them the one implemented in Panama.

The main advantage of radial approach is the negotiation process or agreement modification that makes it easier to negotiate or modify a bilateral agreement than a multipart one. Additionally, this allows commercial bodies to stay away from a direct relationship with supplier communities, if any or from certain local institutions in order to avoid problems related to the direct presence of transnational pharmaceutical or biotechnology companies.

In this context, if the central organization of the radial structure has credibility and prestige it is easier to negotiate access to communities or governmental authorities than for a company. The main disadvantage of the model is that participation is restricted to who participates fully in each contractual agreement, leaving others unrelated and unlikely to make relevant legal claims. This is why coherence among the different agreements is recommended.

2.1 General rules for projects of the "International Cooperative Biodiversity Group"

It is important to mention the general rules that ICBG projects must have, both in terms of procedures and in terms of contract contents. The following are pointed out for their relevance in understanding this case study:

i. Some of the basic elements of the ICBG include:
   - Active participation of individuals and organizations of the host country in the planning and other stages of the project.
   - Multidisciplinary research of global and local diseases.
   - Local training and infrastructure on biodiversity management and drug discovery.
   - Biodiversity inventories and monitoring.
   - Implementing equitable agreements on intellectual property.

ii. ICBG principles on access, fair benefit-sharing and intellectual property rights are:
   - Disclosure and prior informed consent of country participants.
   - Clear stipulation of rights and obligations.
   - Protection of inventions by patents and other mechanisms.

- Fair benefit-sharing with the appropriate participants of the country of origin.
- Information with a flow that balances the needs of participants and the protection of owners.
- Implementation with respect and compliance with both relevant national laws and international conventions.

All approved projects must follow the principles in the design of their contractual agreements. In this framework, the Panama ICGB Program was launched on October 1998 sponsored by the "National Health Institute" of the United States of America, the "National Science Foundation" (NSH) and the Department of Agriculture of this country. The goal of this initiative lies in researching for drugs in Panama's biodiversity for the different types of diseases, among them: Chagas disease, malaria, cancer and leishmaniasis.

In this scenario, it must be clarified and indicated that the "International Cooperative Biodiversity Group" Program is based on the submission of competitive proposals that are assessed by a panel to determine whether they are funded or not, and projects approved and funded last for five years.

3. "International Cooperative Biodiversity Group" and Panama: collaborating on research of biodiversity and its by-products

This case study will focus on the collaboration or current project between the ICBG and Panama conducting an analysis of what is relevant to the overall process because it is the same scientific research with specific variables. The reviewed documents reveal that the first ICGB from Panama was approved in the second round of proposals in September 1998, with the name "Ecologically Guided Bioprospecting in Panama" and in September 2003 its continuation was financed calling it "Bioassay and ecology directed drug discovery in Panama" valid up until 2008.

During the period from 2009 to 2014 a new phase of the ICBG is being developed with the intervention of National Institutes of Health of the United States of America based on the two previous projects. In this new phase the objectives include the discovery of promising compounds derived from Panama´s biodiversity with a possible therapeutic and agrochemical application.

The objectives of the ICBG implemented in Panama are: to improve human health by discovering new agents or compounds to treat diseases in developed and developing countries; to promote scientific and economic activities in the country through a fair benefit-sharing of drug innovation processes and research for conservation; to preserve biodiversity by way of understanding and valuing biological organisms, and to develop national capacities to manage natural resources.

Summarizing, the purpose of the ICBG is to find new compounds from microorganisms in Panama to treat diseases such as: cancer; tropical diseases; central nervous system disorders and others, using a set of traditional and innovative tests. Efforts include the development of scientific capacities and infrastructure because ecological concepts guide the collection and cultivation of microorganisms that are the source for tests and other research activities where required extracts are produced.

3.1 Actual or potential use of genetic resources in by-products

The Panama ICBG seeks to discover new compounds derived from biodiversity in two basic sectors, the pharmaceutical sector and agrochemical one; the latter is new because at the beginning the aim was to collect plants. This is how in 2003 the second ICBG round started and decided to include other genetic resources like marine species.

Nowadays, collected biological diversity includes: tropical plants; endophytic fungi; cyanobacteria; marine organisms including algae and vertebrates, and microorganisms among the main ones. The selection of collected organisms is based on basic research as well as ecological or natural history on biodiversity and its elements.

The collection is performed in the "Smithsonian Tropical Research Institute" (STRI), focusing on: plants; endophytic fungi; marine cyanobacteria; microalgae; coral and sponges. Samples are collected in protected areas of Panama, and then extracts are prepared to be used in bioassays. The development of the first processes in Panama were implemented in laboratories of the Institute of Advanced Scientific Research and High Technology Services (INDICASAT), then the active compounds were purified there, in the University of Panama and universities in the United States of America.

4. Legislation applicable to the access to genetic resources in Panama

The General Environmental Law 41 of July 1, 1998, contains a generic rule that establishes literally: "The National Environmental Authority (ANAM) is the competent body based on the provisions of this Act and its regulations to rule and regulate and control access to and use of biogenetic resources in general, except for human species, respecting the intellectual property rights. To fulfill this function it will develop and introduce legal instruments and/or economic mechanisms. The right to use natural resources does not entitle their holders to use the genetic resources contained therein." (Art.72).

The rule is a useful starting point for further regulations that will set the guidelines on access to genetic resources and a fair benefit-sharing, with a consultancy in course to conclude with this proposal. Law 41 of Panama (Art. 2) defines genetic resources as: "a set of hereditary molecules in organisms whose main function is the generational transfer of information on the natural heritage of living creatures. Its expression yields a set of cells and tissues that create a living being". It also specifies bioprospecting as: "exploring wilderness areas in search of species, genes or chemicals derived from biological resources to obtain medicinal, biotechnological and other products".

Law 41 reiterates in its Art. 62 that natural resources are of public domain and social interest without prejudice to the rights legitimately acquired by individuals, defining public domain in Law 24 as: "the legal regime to which wildlife is subject to and grants its exclusive domain to the State. Its use and exploitation are done according to administrative procedures established in the objectives of this Act which is wildlife's conservation". In addition, Art. 63 of Law 41 establishes that "indigenous regions and municipalities where natural resources are exploited or extracted will have the duty to contribute to its protection and conservation according to the parameters established by the ANAM together with regional indigenous authorities and current legislation."

Law 24 of June 7, 1995, regarding Wildlife Conservation states that it is part of Panama's natural heritage and declares of public domain its: protection; conservation; restoration; research and management; development of genetic resources; species, breeds and varieties of wildlife; making it clear that it is all for the benefit and protection of natural ecosystems including those species and varieties introduced in the country and whose adaptation process has undergone genetic changes in different ecosystems (Art. 1). This law also regulates wildlife collection permits for scientific, personal, commercial, reproduction, hunting or fishing reasons, granted by the Department of Protected and Wildlife Areas of the National Non-Renewable Natural Resources Institute (INRENARE), currently ANAM according to Art. 39.

Permits for wildlife harvesting, hunting and fishing in protected areas or indigenous reserves would be the INRENARE's responsibility together with indigenous authorities (Art. 50). Some provisions of the Law provide for the participation of locals in the research (Art. 19), with additional considerations to its regulation in Executive Decree 43 of July 7, 2004, being the most important the granting of export, import, pre-export, pre-import, or transit permits related to wildlife species for its validity and application.

Legislation allows for the establishment of agreements for the development of programs and activities to promote the improvement, development and protection of wildlife with public and private entities; collection for commercial, personal, reproductive, scientific or other purposes. Also, the National System of Protected Areas may award grants of administration and services to municipalities, provincial governments, centers, foundations and private companies implementing them according to previous technical studies. It does not apply to ABS cases.

Management and exploitation of marine resources in coastal areas will be the responsibility of the Ministry of Commerce and Industry or of Maritime Authorities in Panama having a shared responsibility with ANAM. Exception applies in cases where priority is given to marine ecosystems with high levels of biodiversity and productivity such as estuaries, coral reefs, wetlands or other breeding areas. All access permits are regulated by Executive Decree 25 of April 29, 2009, which regulates Art. 71 of the Environmental Law of Panama. ANAM is the competent national authority through the Access Unit to Genetic Resources assigned to its Department of Protected Areas and Wildlife, because an access contract is required between this entity and the applicant including fair benefit-sharing clauses.

Law 20 of June 26, 2000, refers to the: "Special regime of collective rights of indigenous peoples and its regulation by Executive Decree 12 of March 20, 2001. A sui generis protection system for traditional knowledge, limited to indigenous peoples is established and aimed at protecting folklore and other traditional cultural expressions"; according to the World Intellectual Property Organization (WIPO) folklore means "traditional cultural expressions". With respect to intellectual property, and particularly to patent laws, Law 35 of May 10, 1996, stands out.

5. Participants of the project conducted in Panama by the "International Cooperative Biodiversity Group"

Participants of the ICBG in Panama are known for being constant throughout the research process since 1998, unlike some foreign members who participated only at the beginning. Thus, there is a model agreement to be used with academic collaborators, not with business partners, signed in this Project by the Smithsonian Tropical Research Institute STRI and other institutions.

In this context of collaboration, the following are the different stakeholders identified in Panama which stand out during the process of the project in accordance with their participation:

i. Main institutions and key partners in Panama:
   - STRI establishes agreements with the ANAM of Panama and is the receiving institution for the different funding.
   - University of Panama.
   - Institute of Advanced Scientific Research (INDICASAT).
   - NGOs cooperating with issues related to biodiversity conservation.

ii. The following academic collaborators and significant foreign scientists:
   - University of California, San Diego.
   - University of Utah.
   - University of South Florida.
   - University of California, Santa Cruz.
   - University of Oregon.
   - University of Arizona.
   - Scripps Institution of Oceanography.

iii. Industrial and business partners:
   - Eisai Pharmaceuticals.
   - Dow AgroSciences.
   - Novartis Institutes for BioMedical Research not participating in the current ICBG.

iv. Government institutions participating:
   - National Environmental Authority of Panama.

5.1 Project activities and programs at a national and international level

The initial program of the ICBG signed legal agreements with the ANAM of Panama, the University of Panama and the Gorgas Memorial Institute for Health. Also, insect inventories and community health studies were considered.

The previous project was established on the basis of four associated programs (AP):

i. AP 1: STRI botanists collected and identified plants obtaining chemical extracts from them and from other organisms. Equivalently, it managed the database with information on collections and material transfers.

ii. AP 2: INDICASAT scientists performed biological tests to determine whether the extracts have activity for treating cancer and other diseases.

iii. AP 3: scientists of the University of Panama purify the extracts with high activity levels to discover active compounds and obtain their chemical structure.

iv. AP 4: STRI scientists collect and identify marine plants and invertebrates. Currently, the

main ICBG activities (2009-2014) are:

i. STRI scientists collect and identify plants, algae, endophytes and marine invertebrates to obtain extracts.

ii. INDICASAT scientists conduct biological tests with the extracts to show if they have activity against various diseases using different techniques, the ones that show high levels of activity are reviewed through chemicals at the University of Panama or INDICASAT to be purified and to determine their active compounds.

iii. Studies of foliar endophytic fungi, algae, cyanobacteria and marine invertebrates, as well as bioassays to counteract the dengue virus, are conducted in Panama and are complemented in universities and research centers in the United States of America with the following AP:

- AP 1: collection and cultivation of microorganisms, University of Utah.
- AP 2: conduction of biological assays of microorganisms, University of South Florida.
- AP 3: elucidation and structural isolation of natural bioactive products, University of Panama
- AP 4: revelation of drugs from freshwater and marine microorganisms, University of California, San Diego.
- AP 5: biodiversity conservation in Panama, STRI.

5.2 Contractual agreements among collaborators and legal implications

Currently, because of how the ICBG of Panama is developed, it is important to distinguish the different types of existing contractual agreements:

i. The STRI has contracts with the various collaborators, among them scientists from Panama and foreign entities, and industrial collaborators under confidential agreements.

ii. The STRI has signed an agreement with ANAM related to access to genetic resources and a fair benefit-sharing. This document is a public instrument.

In this perspective of legal contracts, a clarification is required on how provisions in the ANAM agreement relate to other agreements to complete a scheme of contractual relations. The first document was signed on April 29, 1999, among ANAM and STRI, with the foregoing approval of the ICBG Project. But in 2009 another document was signed and it will be valid until 2014, determining how fair benefit-sharing, intellectual property and other issues will work.

The most relevant provisions of the first agreement signed in 1999 are:

i. The agreement signed between directors of the institutions is called "Agreement to allow the collection, transfer, export and use of biological materials", having as its legal base the General Environmental Law.

ii. The ICBG in Panama adopted the radial scheme.

iii. The first clause contains a series of definitions such as: important events; access rights; derivatives; net income; intellectual property; research plan and environmental trust among the main ones.

iv. The second clause refers to the powers of the ANAM.

v. The fourth clause states as an objective of the Agreement: "the collection, extraction, transfer, export and use of biological material", and regulates the fair benefit-sharing arising from the research.

vi. The fifth clause examines the importance of biological resources to Panama correctly pointing out the efforts to improve their knowledge.

vii. The sixth clause contains some benefits even of non-monetary nature.

viii. The eight clause expressly mentions the ICBG.

ix. The ninth clause regulates the procedures for collecting material because it is required to submit an application following the procedures established in Panama and their approval will be valid for one year. Each sample collection should be of 100 grams, unless a higher amount is approved and it only applies to STRI Staff. The procedure includes a payment for a permit of US$ 20 making it clear that it is not for samples or materials.

The application is approved in an average period of four weeks, and if denied it should be justified specifying that the authorization grants the right of collection to the STRI and includes minimizing the environmental impact during the collection.

x. The tenth clause regulates the authorization for the use, transfer and export of material.

xi. The eleventh clause regulates the procedural terms and issues under which the transfer is made.

Paragraph b establishes obligations concerning an industrial potential partner or whoever is in possession of non-profit material, implemented when the term of five years mentioned in the Agreement expires.

xii. The twelfth clause establishes the percentage of benefits stating that: "all STRI net income associated with this agreement will be distributed as follows: 20% will be paid to the National Wildlife Fund, 30% to the Environmental Trust and 50% will be divided equally between the STRI and each participant partner in Panama".

xiii. The thirteenth clause regulates the second component of monetary benefits arising from access rights, referring to the income provided to the STRI by an industrial collaborator for scientific or research projects and as part of the Agreement.

The fair benefit-sharing is agreed as follows: 40% for the Environmental Trust, 30% for the National Wildlife Fund and 30% will be set aside by the STRI to support research and conservation activities in Panama.

xiv. The fourteenth clause comprises payment and audit terms.

xv. The fifteenth clause includes confidentiality.

xvi. The sixteenth clause encodes intellectual property rights.

xvii. The twentieth clause mentions industrial and non-profit collaborators stating that the ANAM should be notified about any agreement signed through a copy of it.

xviii. The twenty-first clause states the compliance of requirements of the ICBG program understanding that no provision of the Agreement should be inconsistent with the established terms.

xix. The twenty-second clause systematizes the progress reports.

xx. The twenty-sixth clause talks about the termination of the agreement and other issues.

The most salient provisions of the agreement valid since 2009 are:

i. The third clause recognizes the importance that biological resources and diversity have by conducting biological researches and related studies to improve their knowledge, appreciation, conservation and use.

ii. The fifth clause states that the STRI should send ANAM a list of species of interest if known, prior to the completion of the collection; if unknown, it should render a written report on the progress level of the classification. The STRI requires to have a record of the biological material collected and to minimize the environmental impact of activities. Furthermore, it indicates that no associated traditional knowledge be included in bioprospecting projects.

Collection in protected areas is done prior approval of the ANAM Genetic Resources Unit established by Decree Nº 25 in 2009, and other competent entities, and permits and their duration are being processed according to current regulations.

iii. The sixth clause regulates the uses of collected material prohibiting its sale and allowing the conduction of researches and assays.

iv. The seventh clause encodes the agreements of STRI with non-profit academic and industry collaborators, especially for the development of researches and the delivery of samples. Each one of them will sign an individual contract and the ANAM will have copies of it.

v. The eight clause deals with the transfer and export of biological material with Panama as county of origin. A Transfer Agreement is required both within and outside the country. In case of exporting to non-profit industrial or academic collaborators an ANAM authorization is always required provided that they are members of the Agreement. This request could be avoided if there is an agreement for the provision of services among the STRI and a third party.

vi. The ninth clause regulates the custody of biological material throughout the agreement since the STRI must report all things in its or in their collaborators' possession upon termination. According to this, every taxonomic sample which has not been used upon termination of the agreement should be returned or destroyed.

vii. The tenth clause regulates a fair benefit-sharing arising from net income, accompanying all access applications within the ICBG as follows:

- In the event the institution making the discovery is located in Panama and is a member of the ICBG in the country, or a non-profit or academic collaborator, it will receive 50% and the other 50% will be for member institutions as follows: ANAM 25%; University of Panama 25%; INDICASAT 25%, and STRI 25%.
- In the event the institution making the discovery is located in the United States of America it will receive 50% and the other 50% will be distributed as follows: institution that made the discovery 30%; non-profit or academic collaborating institutions 20%; institutions members of the ICBG in Panama together with ANAM 50% equal shares.

viii. The fourteenth clause regarding patents and intellectual property states that the latter could be developed in connection with or as a result of the agreement, with the STRI and/or its collaborators as patent protectors if they consider it appropriate and according to the terms of the agreements.

Intellectual property includes but is not limited to, new chemical entities such as: molecules; genes; sequences; parental lines; discovered biochemical processes and agricultural diagnostics among other goods.

ix. Various articles regulate issues like: payment terms; audits (Article 11); confidentiality (Article 12); publications (Article 13); authorized representatives (Article 15); reporting (Article 16); responsibility assignment (Article 17); relationship between parties (Article 18); duration and termination (five years extended or modified by mutual agreement or *addendum*); subsequent uses of biological material (Article 20), and various clauses of full agreement, dispute resolutions and transitory provisions.

6. Benefit sharing in Panama and the development of the project

In terms of the results obtained by the ICBG project, there is a significant consensus regarding its achievements and benefits since it contributes to Panama's society, as well as to the conservation and sustainable use of biodiversity.

Research funding has been of more than seven and a half million dollars over the course of 15 years, but marketable results from its products are yet to be seen. Currently, studies developed have identified active compounds of interest for cancer and leishmaniasis treatment.

The ICBG traceability mechanisms are characterized for generating databases with information on the different compounds and samples, and they stand out because this scheme contributed for the improvement of samples and extracts as well as other materials that are held by collaborators abroad

6.1 Impact of the project at a local socio-economic and/or institutional level

A key aspect of the ICBG in Panama is the investment in national research institutions because they cooperate in bioprospecting activities and studies developed in their laboratories with the participation of scientists and students. The focus of this group in its three prior versions was characterized for: the construction and equipment of high technology laboratories; and staff training for bioprospecting, scientists and students training, with some scholarship holders abroad to study for master's and doctoral degrees in related fields such as chemistry and biology among others.

Some ICBG activities in the country are related to training scientists to develop new bioassays and who will later share their experience with researchers from other Latin American countries when they are visiting Panama institutions for learning purposes. Thus, the INDICASAT develops bioassays for a series of tropical diseases like leishmaniasis, malaria and Chagas disease among others. This allows costs reducing, profits assessment and natural products activity testing. Novel bioassays are performed collectively for cancer treatment.

The project created databases and libraries of compounds in association with CENTAURI BIOTECH SL to be used by national authorities and other institutions on biodiversity researches. The declaration of the Coiba Island as National Park in the Pacific coast stands out where the first collections of marine and terrestrial materials are taken. In this place vegetation is well preserved because it was a penal colony and once it was shut down the ICBG supported inventory and research activities in the protected area and its vicinity. Some of this scientific evidence was used in 2004 by the Panamanian Parliament and gave the area the status of National Park, later in 2005 the UNESCO Convention declared it as a Natural World Heritage Site of Humanity.

ICBG participants isolated promising bioactive molecules in major therapeutic areas such as the ones causing parasite-diseases and cancer. Research in drug discovery and other compounds is complemented with the development of biological inventories, conservation initiatives and dissemination of information. At the same time, Panamanian professionals give lectures on the importance of biodiversity conservation generating larger public awareness and sensitization of their services for society. In recognition of this scientific model and the development of capacities the Global Environmental Fund GEF through the Nagoya Protocol Fund decided to assign the ICBG the first funding granted under the Nagoya's Fund scheme.

The main impacts of the project in institutional terms for conservancy, biodiversity and local economy are as follows:

i. ICBG's direct investment for approximately US$ 7'500.000, plus a financial aid of other sources that could reach an amount of US$ 1'860.000.
ii. Distribution of funds to Panamanian institutions.
iii. Acquisition of infrastructure and equipment.
iv. Training for students and attendees. Some have postgraduate studies in scientific areas.
v. Repatriation of local talent.

vi. Identification of some promising compounds such as Coibamide and Chagresnol so called in distinction of Panamanian places.

vii. Instruction on several activities and lectures.

viii. Collaboration of national institutions with universities and research centers of the United States of America.

ix. Training of human resources and talents.

7. Intellectual property rights and patents

Currently there are eight patent applications in the United States of America; at least two have as their main inventor a Panamanian scientist. One of the most important ones is related to leishmaniasis treatment (PCT/US2003/027469).

The most outstanding patent as a result of promising experiments and related to an active molecule for treating cancer was collected in the National Park of Coiba.

No conflicts or agreements reached upon them were found, and at some point there was a comment about the content of the STRI-ANAM Agreement of 1999 suggesting better terms for the Government of Panama.

8. Lessons learned

The following are the main lessons learned, especially because of the legal difficulties and complexities encountered in the project:

i. Continuity of biodiversity research processes, with a long term ICBG of almost 15 years and showing that it takes time to get the results and concrete by-products of biochemical and genetic resources. It also reaffirms the difficulties of carrying drugs or other goods to markets because expectations are challenged regarding the possible monetary benefits of bioprospecting due to a high risk and time to merchandise the products.

   An important lesson is the value of non-profit benefits such as training, staff coaching and training, among others.

ii. Regarding the Protocol of Nagoya a lesson of this ICBG in the impact of having national counterparts with sufficient scientific and technical capacity is pointed out because it maximizes the purpose of relationships received by ABS.

   The existence of a group of national institutions can enhance the results of technology transfer and create greater endogenous research capacities.

iii. Project recognition for the development of monitoring mechanisms to use biochemical and genetic resources, which together with the Case in Costa Rica would provide experience on this subject. Again, the importance of having national counterparts in the research is pointed out for they are essential to increase efficiency in monitoring the flow and use of genetic resources.

iv. After analyzing this ICBG no unexpected effect was identified on access rules implemented in 2006 or modified in 2009.

The renegotiation of an agreement between the STRI and the ANAM defined the existence of a scheme of access permits managing the activity of bioprospecting in Panama with this project.

v. The ICBG focus is displayed in the collection of biological material in protected areas without using traditional knowledge, if this decision works out, it prevents the generation of incentives for the conservation in areas that could be more critical and vulnerable due to the lack of a specific protection regime.

vi. Considering the different sides of the project the impact in terms of derived benefits for conservation it is not yet clear beyond what was received indirectly through the awareness of the biodiversity value, lectures and other mechanisms.

9. Bibliography

Coley, P.; M. Heller; R. Aizprua; B. Araúz; N. Flores; M. Correa; M. Gupta; P. Solis; E. Ortega-Barría; L. Romero; B. Gómez; M. Ramos; L. Cubilla-Ríos; T. Capson y T. Cursar. 2003. Using Ecological Criteria to Design Plant Collection Strategies for Drug Discovery. **Frontiers of Ecological Environment** **1(8): 421-428.** Cragg, G.; F. Katz; D. Newman y J. Rosenthal. 2012. The impact of the United Nations Convention on Biological Diversity on Natural Products Research. **The Royal Society of Chemistry** **29(12): 1407-1423.**

Kursar, T.; C.C. Caballero-George; T.L. Capson; L. Cubilla-Rios; W.H. Gerwick; M.V.Heller; A. Ibañez; R.G. Liningotn; K.L. McPhall; E. Ortegea-Barría,; L.I. Romero y P.D. Coley. 2007. Linking Bioprospecting with Sustainable Development and Conservation: The Panama Case. **Biodiversity and Conservation 16: 2789-2800.**

10. Websites

International Cooperative Biodiversity Group. 2013. **Aspectos generales y principios de funcionamiento.** Online at: <www. icbg.org/program>. Last viewed: February 10, 2013.

11. Interviews

Luque, Darío. Com. pers. 15/02/2013. Unit of Genetic Resources of the National Environmental Authority. **Interview on the legal and institutional framework of Panama.** Panama, Panama.

Luis Cubilla, Com. pers. 15/02/2013. Scientist, University of Panama. **Interview on the development and evolution of the Panamanian ICBG**. Panama, Panama.

Case Study in Peru

Gabriel Ricardo Nemogá-Soto

Registry of collective knowledge associated with biodiversity

1. Introduction

Since 1996, through Decision 391, countries of the Andean Community established a Common Regime on Access to Genetic Resources recognizing the right and power of indigenous, Afro American and local communities to decide on their traditional knowledge, innovations and practices associated with genetic resources and its by-products. In the same rule, transitional provision eight set a period of three months to establish a special regime or a harmonization standard to enforce the right and power to decide; however, after 17 years the intended purpose and protection have still not been implemented.

In 2005 the Andean Community of Nations (CAN) published the results on the analysis of a sui generis regime for the protection of traditional knowledge, innovations and practices of indigenous peoples related to biodiversity and cultural aspects and folklore. Globally, since 2001 the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (CIG) of the World Intellectual Property Organization (WIPO) conducts activities to analyze gaps and possible solutions to an articulated proposal for the negotiation of States. This case study focuses on a system of registry of collective knowledge in Peru.

2. Potential use of genetic resources and their by-products

Collective knowledge associated with the use and properties of biodiversity in indigenous and peasant communities in Peru is framed at a legal level with preventive mechanisms. The objective is to ensure compliance with CBD's third objective on fair equitable benefit-sharing arising from the use of traditional knowledge and in 2002 the government established a registration system.

The details of the established system, its components and legal, technical and political matters related to its development and implementation are described in a technical paper called "The need to integrate indigenous worldviews in protection systems of traditional knowledge: an approach from biocultural diversity" (Tobin and Swiderska 2001). The analysis on this case study is supported by documentation prepared by the National Institute for the Defense of Competition and the Protection of Intellectual Property (INDECOPI) and interviews with its officials.

Nemogá-Soto, G.R. 2013. Registry of collective knowledge associated with biodiversity. In: Rios, M. and Mora, A. (Eds.), **Six case studies in Latin America and the Caribbean: Access to genetic resources and benefit-sharing.** UICN-PNUMA/GEF-ABS-LAC. Quito, Ecuador. Pp. 105-116.

3. Actual and potential use of collective knowledge

The analyses conducted established that collective knowledge of indigenous and peasant communities have a potential use in: agriculture, nutrition, natural medicine, cosmetics and vegetable dyes among others. They are associated with plant species in the Amazon, namely: *cocona* (*Solanum sessiliflorum*), *sangre de grado* (*Croton lechleri*) and *chuchuhuasi* (*Maytenus macrocarpa*), and in the Andean Region represented by quinoa or *quinua* (*Chenopodium quinoa*) and a diversity of the *Solanum* type.

In this context it should be noted that Peru is a mega diverse country hosting one of the centers of origin and variety of crops that contribute to global. It also has a confluence of indigenous peoples, Afro descendant and peasant communities in its territory who contribute dynamically to cultural diversity and biological richness.

To summarize, a careful analysis should be done of the actual and potential use of collective knowledge associated as object of research, but in some cases it is accessed breaching: permits; prior informed consent and mutually agreed terms and legal ownership of intellectual property rights (IPR), all of which must be met according to the established requirements in the national and Andean regional legislation (Law 27811 of 2002, Decision 486/2000, Art. 26, Paragraphs h, i; ILO Convention 169 of 1989).

4. Bioprospecting project actors

In Peru, during the implementation of the "International Cooperative Biodiversity Group" (ICBG), there were reasons to design a registry of collective knowledge system in response to a series of debates (Tobin and Swiderska 2001; Clark, Lapeña and Ruiz 2004). The Peruvian case excelled in the Latin American and Caribbean region because it is one of the first bioprospecting agreements involving indigenous collective knowledge related to biodiversity resources.

The bioprospecting project in Peru showed the need of Peruvian indigenous communities to overcome a situation of uncertainty and vulnerability especially in future prospective negotiations. Thus, a part of the response is the registry of collective knowledge system and the established legal parameters for its access. The actors involved in the country's strategy to protect collective knowledge and achieve a fair benefit-sharing derived from its use are many, including institutions and organizations involved in researching protection, design, development and management options of a particular system.

Various actors participated in the initiative for protection of collective knowledge, among them: public institutions; academic sectors; NGOs; companies and indigenous peoples. In this regard it should be said that the process on intellectual property was led by the Peruvian authority INDECOPI together with: National Natural Resources Institute (INRENA); National Agricultural Research Institute (INIA); National Environmental Council (CONAM) and the Peruvian Society for Environmental Law (SPDA). Some activities such as meetings and workshops related with the discussion and dissemination of the initiative were characterized by opening spaces for participation and comments reception from representatives of indigenous organizations, researchers and scientific institutions.

5. Legal instruments and fair benefit sharing

The strategy followed by Peruvian institutions aims at ensuring the protection of collective knowledge and the fair and equitable benefit sharing begins with the development and implementation of a regulatory framework expressed in two laws. Law 27811 of 2002, which establishes a regime of protection for collective knowledge of indigenous peoples linked to biological resources. Law 28216 which establishes a National Commission for the Protection of Access to Biological Diversity and to Collective Knowledge of Indigenous Peoples in Peru (Valladolid 2013). In this legal scenario, the first law mentioned refers to a system of registry of collective knowledge to prevent misappropriation and to establish an institutional platform that ensures a fair benefit sharing arising from the use of this knowledge with the original creators; and the second Act will complement the first formalizing the action of the State and civil society institutionally against biopiracy.

Ever since Patent No. 6428824 was issued by the United States Patent and Trademark Office to "Pure World Botanicals Inc.", on a technical innovation based on a plant species of Peruvian origin known as *maca* (*Lepidium meyenii*), government authorities and civil society in coordination with the INDECOPI created a commission to identify cases of biopiracy gathering Ministerial entities; commissions of the export and environmental sectors; research institutes on natural resources, agriculture and health; indigenous organizations; representatives of the industrial sector; and NGOs (OMPI 2005).

The establishment of this Peruvian system did not include a prior consultation with indigenous peoples but their organizations were involved in the design process, discussion on a protection regulation, and even its issuance as a national Act. Intervention of indigenous communities through a registry of collective knowledge and an increase on applications between 2006 and 2012 demonstrates that the initiative is recognized by the main actors.

6. Project description

The protection system implemented in this country as a defensive mechanism against misappropriation is based on the registration of collective knowledge associated with biodiversity and genetic resources of Peruvian origin. Therefore, three types of registration were established through Law 27811 of 2002:

i. The National Public Registry of Collective Knowledge of Indigenous Peoples includes all publicly available knowledge and the one declared as such by the communities.

ii. The National Confidential Registry of Collective Knowledge of Indigenous Peoples includes all knowledge that the communities demand to keep as confidential.

iii. Local Registries of Collective Knowledge of Indigenous Peoples correspond to registries that communities choose to establish locally under their administration and according to their uses and customs, unlike the first two managed by INDECOPI. This last type of registry is implemented by the communities themselves.

6.1 Activities for the registry of collective knowledge

When considering the original objectives of the protection system especially to prevent improperly granted IPR on innovations related with collective knowledge of indigenous peoples, activities were focused on making effective their registry. Also the law, its components and potential benefits were spread aiming to gain the trust of the communities and indigenous peoples through the following:

i. Identification, search and registry of collective knowledge on uses and application associated with biodiversity, spread or of public domain, with or without consent of the communities.

ii. Sensitization with indigenous leaders and representatives about the risks of losing traditional knowledge and persuade them about the benefits of the law.

iii. Preparation of data collection equipment in the field represented by researchers, indigenous representatives and parataxonomists.

iv. Preparation of material in Spanish and indigenous languages through written and sound diffusion.

v. Diffusion about law contents through events with indigenous peoples, and public, academic and corporate sectors.

vi. Submission and support of the benefits of the system and its rationality at an international and regional level.

vii. Creation of an electronic portal with updated data and relevant to indigenous peoples and potential users on Traditional Knowledge of Indigenous Peoples (CTPI). In this site http://aplicaciones.indecopi.gob.pe/portalctpi/, there is information on how the registry operates and functions and on documents on experiences and rights of indigenous peoples and communities.

viii. Dissemination of visits, group discussions and events within the communities on the description, operation and training, socialization of objectives, functioning and participation of the registry of collective knowledge.

7. Legislation and fair benefit sharing

Law 27811 established an Indigenous Peoples Development Fund (IPDF) as a compensatory mechanism associated to the registry of collective knowledge and it also provides as resource sources: national budget; international technical cooperation; donations and fines for offences committed in the use of collective knowledge. A specific income would be a percentage of economic benefits from royalties of no less than 10% per cent of the gross sales of products developed directly or indirectly from collective confidential knowledge. Additionally, royalties (not fixed) for gross sales of products developed from knowledge of public domain in the last 20 years are expected (Art. 8 and Art. 13, Law 27811).

Benefits are distributed through financing of projects in the communities that do not require having a registry of their knowledge in the system. In any case, project funding is delegated to the Administrator Committee composed by seven representatives, five from indigenous organizations and two of the National Commission of Andean, Amazonian and Afro Peruvian communities.

The possible amount of royalties is set out in the user's declaration whether for research or industrial application of collective knowledge purposes. Bruno Mérchor, Director of Inventions and New Technologies of INDECOPI said in 2012 that in case of industrial or commercial purposes the community will get paid at least 5% per cent of the products sold, using collective knowledge and a 10% will be assigned to the Indigenous Peoples Development Fund.

As of February 2013, no economic benefits are reported arising from license agreements of collective knowledge and no projects from the Indigenous Peoples Development Fund are financed. However, non-economic visible benefits have been generated under the local and/or institutional socio-economic conditions.

8. Research, follow up and monitoring activities

The registration system of collective knowledge during its operation especially during 2006 and 2012 shows that indigenous communities have filed 1594 applications of which 260 are associated to plant species and some to animal species. A total of 1081 registries of collective knowledge include some that were available because their access is public domain or were published; however, the majority (60%) refer to information not yet published (Table 1).

Communities of indigenous peoples of *Bora* and *Aguaruna* have 357 and 340 applications respectively, representing altogether a 65% of the registries granted by INDECOPI. At the same time, communities from *Ocaina* have a significant place with 128 registries (12%). The high participation from Amazonian communities contrasts with Andean Quechua communities because they only have 27 registries representing 2.5% of the total.

Data obtained until October 2012 regarding registry applications requested and granted do not represent proportionally the richness of collective knowledge of indigenous peoples associated with biodiversity resources, but only the temporary results of a system that is spread with a scope that varies among the different indigenous peoples. For example, the Amazonian indigenous peoples with the highest population are the *Ashaninka* (26.6%), but only two communities, *Kivinakiy* and *Aldea*, have registered collective knowledge contrasting with a (16.6%) from the *Aguaruna Awajún*. In this Peruvian scenario the follow up and monitoring mechanisms would be linked to license agreements for use of collective knowledge but up until now no agreement has been signed and the follow up is made by INDECOPI and the National Commission against Biopiracy (CNB).

Table 1. Registry of collective knowledge in Peru made by Amazonian, Andean, Indigenous and Peasant communities between 2006 and October 2012.

Nº	Community	Ethnicity	Public Registry	Confidential Registry	Public and Confidential Registry	Total
1	Peasant Community of *San Antonio de Montecucho*	Quechua	1	3	0	4
2	Peasant Community of *San Juan de Chito*	Quechua	2	0	0	2
3	Peasant Community of *San Martín de Hercomarca*	Quechua	3	4	0	7
4	Peasant Community of *Vischongo*	Quechua	7	7	0	14
5	Native Community *Bajo Aldea*	Ashaninka	3	22	0	25
6	Native Community *Betania*	Bora	0	28	0	28
7	Native Community *Brillo Nuevo*	Bora	78	135	0	213
8	Native Community *Caco Macaya*	Shipibo-Conibo	0	2	0	2
9	Native Community *Calleria*	Shipibo-Conibo	2	7	3	12
10	Native Community *Estirón del Cuzco*	Murui	2	55	0	57
11	Native Community *Estirón*	Murui	0	10	0	10
12	Native Community *Kivinaki*	Ashaninka	3	23	0	26
13	Native Community Nueva Esperanza	Ocaina	57	71	0	128
14	Native Community *Nuevo Peru*	Bora	43	69	0	112
15	Native Community *Pakun*	Aguaruna (Awajún)	109	87	7	203
16	Native Community *Pucaurquillo*	Bora	0	4	0	4
17	Native Community *Pucaurquillo*	Murui	30	67	0	97
18	Native Community *Wawas*	Aguaruna (Awajún)	75	60	2	137
	Total		415	654	12	1081

Source: Directorate of Inventions and New Technologies of INDECOPI (2012).

9. Impact of the registry system for collective knowledge on local socio-economic and/or institutional conditions

Local socio-economic and institutional conditions in Peru arising as a result of the implementation of the registry system are as follows:

i. The country has a leading experience in designing, establishing and operating a protection strategy for collective knowledge within the IPR.

ii. The adoption of the registry system and its implementation has allowed Peru to participate in debates about collective knowledge and stand out at international and regional levels in different forums for intellectual property, access to genetic resources and biodiversity conservation.

iii. INDECOPI as administrator of the registry system and other Peruvian institutions have developed an effective communication and persuasive strategy achieving an increasingly widespread use of local and indigenous communities.

iv. The operating registry system provides relevant information and can enhance efforts of government institutions and civil society fighting the misappropriation of genetic resources and traditional knowledge.

v. The initiative promotes social and institutional recognition of the value of collective knowledge and INDECOPI's job who received national awards in two competitions. The first in 2007 for a Good Governmental Practices in the category of Social Inclusion, and the second in 2012 in the Recognition to Good Governmental Practices in Executive Power bodies.

vi. The coordination of activities among authorities of intellectual property represented by indigenous organizations, Confederation of Amazonian Nationalities of Peru (CONAP), Indigenous Nationalities Council and Center of Indigenous Cultures of Peru (CRIRAPAQ), and NGOs on the profile of Peruvian Society for Environmental Law (SPDA). Since 2011, INDECOPI has forged an institutional partnership with the Peruvian Amazon Research Institute (IIAP) as a strategy to: promote the conservation of Amazonian biodiversity; support the protection of collective knowledge; ensure the taxonomic identification of associated resources and increase the registry of collective knowledge.

10. National Anti-Biopiracy Commission: Intellectual property rights and status of patents

In the results of the first search of potential cases of biopiracy submitted in 2005, CNB included applications and additional follow up cases regarding patents. Cases were identified in the databases of: United States Patent and Trademark Office (USPTO), European Patent Office (EPO) and the Japan Patent Office (JPO), tracing the following plant species: *hercampuri* (*Gentianella alborosea); camu* (*Myrciaria dubia); yacón* (*Smallanthus sonchifolius); caigua (Cyclanthera pedata); sacha inchi (Plukenetia volubilis)*, and *chancapiedra*" *(Phyllantus niruri)* (OMPI 2005).

By identifying the potential cases of biopiracy the CNB advanced on investigations to corroborate the origin and circumstances of applications and patents granted. On January 2013, 18 cases of biopiracy related to genetic resources of Peruvian origin and traditional knowledge of indigenous peoples were identified, 10 of which were resolved in favor of the Peruvian State thanks to the intervention of the CNB (Table 2).

Table 2. Status of patents identified by the National Commission against Biopiracy in Peru.

Resource	Patent or application	Office	Status
Maca (2010-235533).	"Agent for preventing on treating osteoporosis"	Japan	Abandoned
Maca from *Lepidium*" (WO/0051548).	"Compositions and methods for their preparation	PCT	Rejected
Maca	"Functional food product containing 'maca'" (Publication N° 2004-000171).	Japan	Rejected
Maca	"Ameliorant for sleep disturbance" (JP/2007031371).	Japan	Rejected
Maca	"The manufacturing method and composition of a 'maca' extract" (Kr/20070073663).	Korea	Rejected
Maca	"Testosterone increasing composition" (JP/2005306754).	Japan	Withdrawn
Sacha inchi	"An extract of a plant belonging to the genus *Plukenetia volubilis* and its cosmetic use" (WO/2006/048158).	PCT	Withdrawn
Sacha inchi	"Utilisation d'huile et de protéines extraites de graines de *Plukenetia volubilis* dans des préparations cosmétiques, dermatologiques et nutraceutiques" (FR/2880278).	France	Withdrawn
Camu	"Preserves of fruit of *Myrciaria dubia* (Publication N° 09-215475).	Japan	Abandoned
Pasuchaca	A-glycosidase inhibitor (P2005-200389).	Japan	Abandoned

Source: National Commission against Biopiracy, President M.Sc. Andrés Valladolid Cavero (release January 30, 2013).

11. Lessons learned

The following are the main lessons learned, especially because of the legal difficulties and complexities encountered in the project:

i. The establishment of a national policy and legal framework for positive protection of traditional knowledge linked to international treaties such as: CBD (Art. 8, Paragraph j; and Art. 10, Paragraph c); Convention 169, 1989; Andean regulation on access to genetic resources; general constitutions that protect cultural and ethnic diversity and the United

Nations Declaration on the Rights of Indigenous Peoples of 2007.

The absence of a valid policy and a regulatory framework enables traditional knowledge to be accessed and processed by users as a free access or public available good, without generating compensations or benefits for its original owners and collective creators.

ii. The issuance of a rule to protect traditional knowledge is just the first step in a complex process because it requires to make it effective and to strengthen the mechanism in order to achieve it.

Dissemination and persuasion of the rule on the benefits of the system established for communities through the development of appropriate written and sound material in the community's official language is required. It is also required to seek partnerships with NGOs, research institutes and representative indigenous organizations according to the terms of each region.

iii. Cultural diversity in mega diverse countries is a challenge in terms of identification of methods, procedures, material and institutions that could enable community access and participation.

iv. The operation of the registry system has two fundamental aspects, community participation and registry validation. In the dissemination of the law to persuade key actors about the benefits of registering their knowledge INDECOPI collaborates on one hand with university institutions for the taxonomic identification of resources associated, and on the other hand it promotes the registry in situ of collective knowledge.

In this perspective, INDECOPI makes pilot visits since 2006 to communities in different departments together with NGOs, representative indigenous organizations and research centers who have an impact on indigenous peoples. In the amazon region where the institution has established a strategy of joint work with the IIAP, greater results are reflected as in 2012, 453 registries of collective knowledge will be delivered, and 596 applications are received from indigenous communities in the *Pebas* district, *Mariscal Ramón Castilla* province. Field activities are possible because renowned traditional authorities participate in the process such as the *Apus* and *Curacas* of the Amazonian indigenous peoples.

v. Prospects in terms of access and fair benefit-sharing, as well as the impact on socio-economic conditions of indigenous and local communities, are generated from the participation on the use of collective knowledge to the extent that two conditions are met: firstly, effective access applications by users of registered collective knowledge; and secondly, the negotiation and signing of a license of use of collective knowledge with royalties set for their original owners. Economic benefits for indigenous peoples and locals could also originate from strengthening the FDPI with additional financing sources provided by law.

12. Bibliography

Clark S., I. Lapeña y M. Ruiz. 2004. The Protection of Traditional Knowledge in Peru: A Comparative Perspective. **Law Review 2(3): 755-797.**

Dirección de Invenciones y Nuevas Tecnologías del INDECOPI. 2012. **Ayuda memoria sobre las actividades del INDECOPI en la protección de los conocimientos colectivos de los pueblos indígenas.** Executive Summary. Unpublished booklet. Lima, Peru. 13 pp.

OMPI. 2005. **Patent System and the Fight Against Biopiracy-The Peruvian Experience.** Document OMPI WIPO/GRTKF/IC/8/12. Ginebra, Suiza. 30 pp.

Tobin B. y K. Swiderska. 2001. **En busca de un lenguaje común: participación indígena en el desarrollo de un régimen *sui generis* para la protección del conocimiento tradicional en Perú.** Serie Participación en la Política de Acceso a Recursos Genéticos. Estudio de Caso Nº 2. Earthprint Ltd. Londres, Inglaterra. 78 pp.

Valladolid A. 2013. **Análisis e interposición de observaciones o impugnaciones de los casos de biopiratería identificados.** Comisión Nacional contra la Biopiratería. Unpublished booklet. Lima, Peru. P. 1.

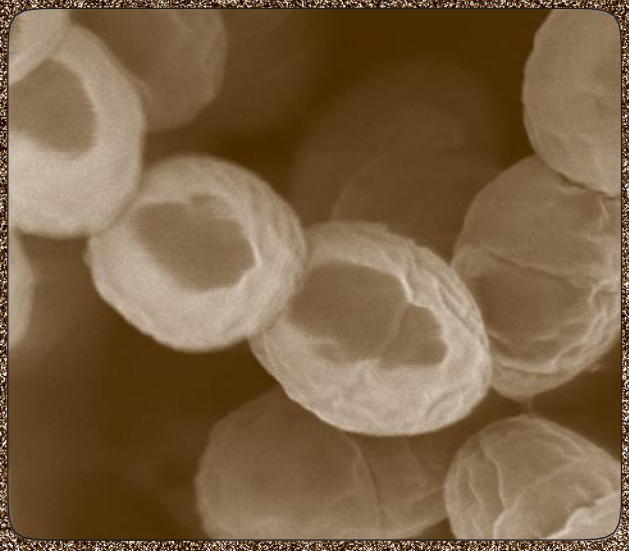
13. Websites

Portillo Z. 27/08/2012. **Peru otorga títulos para proteger conocimiento indígena**. Online at: <http:// www.scidev.net/es/latin-america-and- caribbean/news/per- otorga-t-tulos-para-proteger- conocimiento-ind-gena.html>. Last viewed: November 15, 2012.

ABS in Latin America and the Caribbean:
challenges to implementation mechanisms

Diana Herrera and

Montserrat
Rios



ABS in Latin America and the Caribbean: Challenges to implementation mechanisms

The importance of protecting genetic resources stems from the need for fair and equitable benefit sharing between providers and users (ABS). The intrinsic value generated by traditional knowledge associated with biodiversity, as well as the difficulty in consolidating contractual agreements between different stakeholders, are factors which add to this complexity.

Investigating six case studies considering real experiences in countries in Latin America and the Caribbean as part of the Regional Project-IUCN-UNEP/GEF-ABS-LAC, made it possible to analyze the lessons which contribute with experiences in order to face new challenges. In this sense, the legal advancements reported in the rules, regulations and legislation have contributed in overcoming national complexities and obstructions, because they position the real benefit that genetic resources can generate.

In this sensitive national and international legal context, it becomes necessary to use experiences when facing the challenges for implementation mechanisms in the future. Indeed, time is a catalyst that will one day explain how stakeholder articulation can achieve a correct implementation of the regime on access to genetic resources and fair benefit sharing in Latin America and the Caribbean. Thus, the following insights are suggested as a contribution to move forward:

i. States must overcome the current difficulties and initiate an analysis that will make it possible to award an ABS contract, because even though in the beginning its development will be complex, it will also increase the credibility of the national authorities in the future. In itself, this process will strengthen national regulations governing access permits, which will be reflected in practice.

ii. The processes are sometimes long and unsuccessful in the present, which is why national and international researchers desist from conducting bioprospecting research. Multiple users even opt for misappropriation because the conditions for obtaining an access permit or contract still require greater clarity.

iii. Countries with a well implemented national regulatory system can support others in their development, since it is evident that training is needed by national authorities. Currently, state officials linked with ABS require a high degree of specialization, because it is necessary in procedures of Access to Genetic Resources. This promotes the celerity of processes, it provides legal certainty to users and helps equitable benefit sharing.

iv. The supplier states need specialized laboratories to carry out high level research activities, because this is currently happening abroad and it prevents the participation of scientists and students in the supplier country. In the future, contracts which contribute to equip national institutions with cutting-edge technology must be negotiated, integrating the cooperation of various experts and generating training for local human talent.

Herrera, D. and Rios. M., 2013. ABS in Latin America and the Caribbean: challenges to implementation mechanisms. In: Rios, M. and Mora, A. (Eds.), **Six Case Studies in Latin America and the Caribbean: Access to Genetic Resources and Benefit Sharing.** IUCN-UNEP/GEF-ABS-LAC. Quito, Ecuador. Pp. 117-120.

Success is in sight with trained researchers to systematize databases related to different biodiversity fields, such as chemical compounds in plants. In addition, this reality is a process required to improve traceability and monitoring of samples outside the country as was the case of the "International Cooperative Biodiversity Group" Project in Panama.

v. Considering the importance of genetic resources for indigenous peoples, became proof that bioprospecting research begins with some traditional knowledge. Rural communities depend on biodiversity for a variety of everyday practices, which is the reason why we consider them as protectors and main inventors of several commercial and non-commercial goods that come from nature.

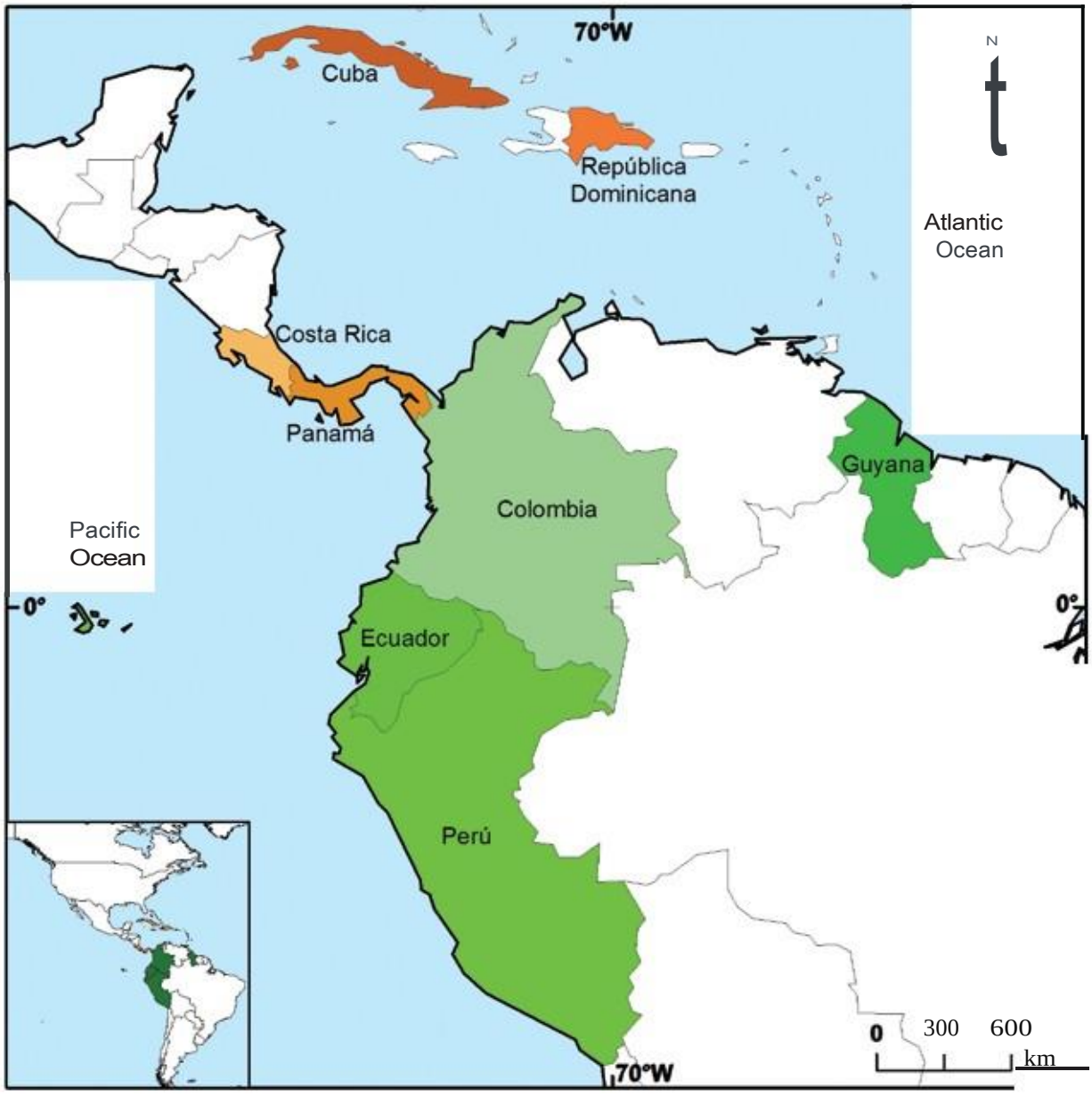
It is clear that today in several countries, it is necessary to establish a policy related to traditional knowledge, because legal measures can protect it. They can keep danger away from ancient cultures and even prevent economic losses for states. Implementing procedures to protect the collective knowledge is urgent, it is a measure which controls misappropriation, while at the same, it; earns the recognition and trust of indigenous peoples, as in the case of Peru. It also creates a system of registry for collective knowledge with a view to obtaining shared benefits with the original creators as well as recognizing their intellectual property rights.

vi. The six case studies show that a more effective commitment is required for the implementation of the Bonn Guidelines, because despite being voluntary are a significant step towards implementing the ABS provisions of the CBD. Future awarded access permits or contracts, should avoid a similar lack of commitment with the implementation of the Nagoya Protocol, because it could lose validity.

vii. Circumstances stemming from the issue of Access and Benefit Sharing do not only affect developing countries –also considered to be megadiverse countries– but also affect the international community. Genetic resources exist within all living organism and, therefore, are distributed worldwide.

At this time, a number of studies related to biodiversity are being conducted, but the problems facing countries on this issue are also great. This is why it becomes apparent that the development of regional cooperation is required to show a unified position which provides support to member countries of CBD.

viii. The great aspiration of this time has been projected onto the Nagoya Protocol, because once it has been adopted, it is expected to be an international treaty that supports the CBD, specifically with regarding the third objective which is fair and equitable benefit sharing arising from the use of genetic resources. In addition, there are other binding legal instruments establishing rules on access to genetic resources that regulate different approaches, determining its scope and facilitating a smooth operation between users and suppliers.



Six Case Studies in Latin America and the Caribbean:
Access to Genetic Resources and Benefit Sharing

.

IUCN Regional Office for South America (IUCN-Sur)
Calle Quiteno libre E15-12 y la Cumbre
Quito- Ecuador
www.iucn.org/sur www.adb.portalces.org