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medio ambiente y desarrollo

Status and potential of commercial bioprospecting activities in Latin America and the Caribbean

Fernando Quezada

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Summary

Commercial bioprospecting activities in Latin America and the Caribbean assume various different forms and approaches in accordance with the target markets, the country context and business models involved. While prospecting for medicinally or industrially valuable substances derived from natural resources is not necessarily a new phenomenon, the systematic search for biologically active compounds in nature has gained a new significance as a component of biodiversity conservation strategies. Furthermore, the increasing availability of new scientific and technological tools have enabled new levels of precision and effectiveness in the identification, collection, processing and utilization of novel substances for applications in medical, agricultural or industrial applications. Accordingly, the companies examined in this study include a range of sizes, commercial strategies and organizational structures which reflect their respective positions in the productive value chain each of the associated industry sectors.

The structure of this study report provides for an introductory overview of biodiversity prospecting in terms of the principles and practices which have defined it both historically and currently. Discussion is offered regarding the stakeholders and the issues involved in the formulation of national policy, particularly with regard to the implementation of provisions of the Convention on Biological Diversity in various countries around the world. These include issues of access and benefit sharing, recognition of indigenous knowledge, prior informed consent, intellectual property protection and others.

The outlook for bioprospecting in Latin America and the Caribbean (LAC) is discussed, highlighting some of the lessons learned from experiences in Costa Rica, Brazil and Mexico. Examples of legislative and regulatory initiatives in these countries are described, including proposed provisions that are still under consideration in Chile. Discussion of the prevailing policy framework in LAC countries serves as a backdrop to profile the firms selected to illustrate the types of commercial bioprospecting activities in the region. Six firms were selected in accordance with specific criteria listed in the study report for this purpose. Finally, general observations are presented along with considerations for future national and regional policy formulation in commercial bioprospecting in Latin America and the Caribbean.

Although there is evidence that opportunities are continuing to open up in certain countries for expanded activities in commercial bioprospecting, it is also perceived that many obstacles remain. In the case of those firms dedicated to bioprospecting for biochemical compounds and biologically active molecules, access to long-term capital and the need for a steady corporate client base seem to be foremost priorities. In the more traditional operations of phyto-pharmaceuticals firms, some of the key challenges are in the need for quality control, purity standards and reliability of materials supply. In both cases, the legislative and regulatory frameworks are still being sorted out and will require continuing input from all relevant stakeholders.

Introduction

1. Study objectives and scope of report

This study is designed to provide a discussion of commercial bioprospecting activities in Latin America and the Caribbean. Reviewing the available literature and focusing on actual business cases, the study explores how bioprospecting relates to traditional and emerging industrial sectors, and what obstacles or public policy issues need addressing in order to ensure the contributions and long-term viability of firms engaged in this activity.

The present report includes an overview of global commercial bioprospecting activities and highlights of the key issues and concerns which have arisen in recent years. This report also offers the criteria used for selection of the individual firms profiled involved in bioprospecting in Latin America and the Caribbean. Associated policy implications and recommendations are offered.

While the study is intended to focus on Latin America and the Caribbean (LAC), not all countries in the region will be included. The study focuses on a selected number of LAC countries where commercial bioprospecting activities are currently being carried out or have been active in recent years: Brazil, Chile, Costa Rica, Mexico, and Peru.

For purposes of providing a general frame of reference, this report also considers bioprospecting activities in selected regions outside of Latin America and the Caribbean where initiatives in biodiversity conservation and bioprospecting guidelines are resulting in a series of national policy directives resulting from the Convention on Biological Diversity. In this regard, the present report includes brief descriptions of bioprospecting activities and related policies in countries like the U.S., Australia, South Africa, Malaysia and others. It also provides background information on the global market context in which these activities take place.

2. Biodiversity and bioprospecting

With the passing of each year, there are renewed efforts for the world to wake up to the destruction of the vast numbers of species of plants and animals, as yet undiscovered, which are becoming extinct. E.O. Wilson, noted Harvard zoologist and the person most identified as the spokesperson against this destruction calls attention to this issue, "If we continue at the current rate of deforestation and destruction of major ecosystems like rainforests and coral reefs, where most of the biodiversity is concentrated, we will surely lose more than half of all the species of plants and animals on earth by the end of the 21st century". Wilson goes on to state that while most of the destruction will take place in the "hot spots" that this destruction is also taking place in other areas of the globe. Much has come to light in recent years about species which live in extreme climates such as the boiling geysers of Yellowstone or the frigid depths of Antarctica (Wilson, 1999).

The term biological diversity or biodiversity has been interpreted broadly by varying interest groups and may encompass levels of complexity including genetic (intraspecies), species (numbers of species) and ecological (community diversity) but is most commonly referred to as the contraction of the words "biological diversity" into the term "biodiversity". However interpreted it generally reflects the common understanding that biodiversity must focus on a common goal of understanding conservation and the sustainable use of genetic resources. (Bull, A. 2004.)

At the United Nations Conference on Environment and Development in Rio de Janeiro the Convention for Biological Diversity (CBD) was opened for signature in June of 1992 and entered into force on December of l993. Currently there are 188 Parties to the Convention of which 168 have signed. The CBD –which will be discussed in greater detail later in this report– is the first global agreement on the conservation and sustainable use of biological diversity. According to the CBD text, "biological diversity" means the variability among living organisms from all sources including, *inter alia*, terrestrial, marine and other aquatic ecosystems and the ecological complexes of which they are part; this includes diversity within species, between species and of ecosystems" (CBD, Article 2).

3. The "diversity of the uncountable"

Man's search for products from nature which will improve the quality of life, cure illness and preserve food dates back thousands of years. This record of discovery on bioactive organisms and compounds coupled with the knowledge that there is a largely undiscovered diversity of microorganism's supports the argument for bioprospecting. According to the CBD Handbook, there are some 1.75 million recorded species recorded on earth while estimates of total numbers may range between 12.5 to 13 million species (CBD Handbook, Special Edition 2002). Microbiologist

Alan Bull refers to the challenge of determining the extent of species in the world as "estimating and comparing the diversity of the uncountable" (Bull, 2004).

TABLE 1
ESTIMATING THE FINANCIAL VALUE OF BIODIVERSITY

Products	Annual Sales (billion US$)	
	Low	High
Pharmaceuticals	75	150
Botanical medicines	20	40
Agricultural produce	300+	450+
Ornamental horticulture	16	19
Crop protection	0.6	3
Biotech (except health & agriculture)	60	120
Personal care & cosmetics	2.8	2.8
Rounded total	500	800

Source: ten Kate K and Laird SA (1999), *The Commercial Use of Biodiversity*, Earthscan Publications Ltd.

A broad spectrum of people representing science, economics, conservation and law warn that biotic resources are under all kinds of threats. Much has been written by conservationists and scientists alike to call attention to the world's incredible shrinking bioresources. In spite of international awareness campaigns, changes in the world's ecosystems are happening at an alarming rate. As pointed out by Wilson and others, there is little information known about the world's existing resources and the knowledge that millions of species that might prove beneficial may be as yet undiscovered.

The Group of Like-Minded Megadiverse Countries (LMMC), representing regions rich in biological diversity and associated traditional knowledge, holds 60-70% of the world's known biological diversity. Convened in Cancun, Mexico in 2002 the 17 members which include Bolivia, Brazil, China, Colombia, Costa Rica, Democratic Republic of Congo, Ecuador, India, Indonesia, Kenya, Madagascar, Malaysia, Mexico, Peru, Philippines, South Africa, and Venezuela, have a vested interest in safeguarding the interests of their countries and peoples and maintain a significant stake in harnessing the potential of biotechnology and bioprospecting for achieving sustainable economic development. Expectations have been raised about the potential of untapped biological riches to locate "green gold". The Megadiverse countries have responded in part to thwart what is feared as a form of "biocolonialism". And, while there have been documented instances of companies from more developed countries taking advantage of traditional medicine sources, a number of major efforts have been scrapped and stumbling blocks placed to prevent scientific discovery. The intertwining of issues related to identifying genetic resources, respecting traditional knowledge and protecting intellectual property rights continues to be one of the most hotly contested issues in negotiations around multilateral agreements (Cancun Declaration, 2002).

A botanical text has recently been rediscovered and may shed light on the identification of traditional species for use in developing new medicines. As noted in the Ambonese Herbal, a seventeenth century text by German Botanist Georg Everhard Rumpf, the scientist collected more than 1300 species native to the Malay Archipelago. After he suffered many personal tragedies and setbacks including earthquake, blindness and shipwreck, his herbal was eventually published in the mid 1700's in Amsterdam. Rumphius, as the botanist called himself in Latin, had interviewed traditional healers to identify those plants which had been deemed valuable. New attention to many of these as yet unstudied texts is yielding valuable information. A top researcher at the Mayo Clinic in Rochester Minnesota is seeking out untranslated herbals from the Ancient Greek to the

Ambonese Herbal. Researchers are noting the name of the species and the probable pharmacological function. For example, medical references in the first volume of Rumphius reveal that the sap of the wild cadju tree may have anti viral properties and may be effective in the treatment of shingles. In the first of the six volumes which make up the Ambonese Herbal 42 plants are listed as having medical properties and 24 of these have been matched with the NAPRALERT, a database which lists all known biochemical and ethnomedical plant references. Nine of these had ethnomedical matches which means that they are known but still may not have been developed within the framework of modern medicine. However, the Ambonese Herbal also mentions nine plants whose names did not appear in the database and thus may serve as source for new drugs. New scientific and computer technology has come into play which will allow thousands of pages to be scanned and cross referenced looking for a possible match with medical databases. Mining these ancient texts may be time consuming but, in the end, yield valuable information (Economist, 2004).

I. Overview of bioprospecting activities

1. Understanding bioprospecting

Bioprospecting is generally defined as the systematic search for and development of new biological resources which may also have commercial value. It includes whole organisms, genes, chemical compounds, extracts, micro and macro organisms, and other products from nature. The goals of bioprospecting include the sustainable use of biological resources through biotechnology and the scientific and socioeconomic development of source countries and local communities. As a systematic search for valuable chemical and genetic constituents of biological diversity, bioprospecting activities continue to be associated with the identification and collection of active compounds existing in nature for purposes of commercial application. Compounds of interest can be found in both animal and plant realms. Targets of interest for bioprospecting in the botanical area include whole plants, useful biochemical compounds, micro-organisms, genes and others.

Often, multinational pharmaceutical companies participate in arrangements which allow for screening selected biological resources from those countries with rich natural resources. If a successful drug were to result from their research, the company would be required to share profits with the country that provided the original biological product. Agreements between the company and country would ensure that benefits return to the community whose knowledge informed the research.

A prospecting program might include collection of the material, screening to protect intellectual property interests and the eventual development of a commercial process or new product which may include modification of the chemical structure to increase efficacy. Bioprospecting may also include downstream testing and the development of other substances derived from the initial discovery. Final stages in this process include manufacturing and plans for larger scale production and marketing of the product. It may be a high risk investment but if successful yield massive returns. According to a survey conducted in l997, 42% of the top 25 drugs in use worldwide have been derived from natural products thus affirming the importance of genetic resources for the pharmaceutical industry. About half the anti-cancer drugs developed since the 1960's have come from nature (Bull, 2004).

BOX 1
EXAMPLES OF IMPORTANT DRUG DISCOVERIES FROM NATURE

A small frog from the rain forests of Ecuador yields a toxin, Epibatidine, a pain killer 200 times more potent than morphine

The anti-malaria drug Quinine is made by boiling the bark of cinchona trees.

Two drugs derived from the rosy periwinkle (found in Madagascar) include vinblastine (used in the treatment of Hodgkin's' disease) and vincristine (used in the treatment of leukaemia).

The powerful cancer chemotherapy drug Taxol was discovered in the pacific yew tree of the North Western United Sates.

Tubocurarine, made from the South American vine Chondodendron tomentosum, is widely used as a muscle relaxant during surgery.

An Argentine soil micro organism has already been turned into an approved drug that fights antibiotic-resistant bacteria, Syncercid.

The heart medicine Ouabain is derived from a West African vine, Strophanthus gratus.

Researchers at Arizona State University have begun human testing for a cancer-fighting drug, bryostatin, made from a marine weed that grows off the California coast.

A Malaysian plant may produce a potential drug to combat AIDS, called calanolide A, which is now at human testing trials.

Of the 3,000 plants identified by the National Cancer Institute as having anticancer properties, 70 percent live only in the tropics.

More than 260 South American plants appear to have potential fertility control applications.

Source: Farnsworth (1988), Foreman (2001) and Locke (2001) in Ward, N. *Sharing Nature's Book of Secrets,* 2004 (unpublished manuscript).

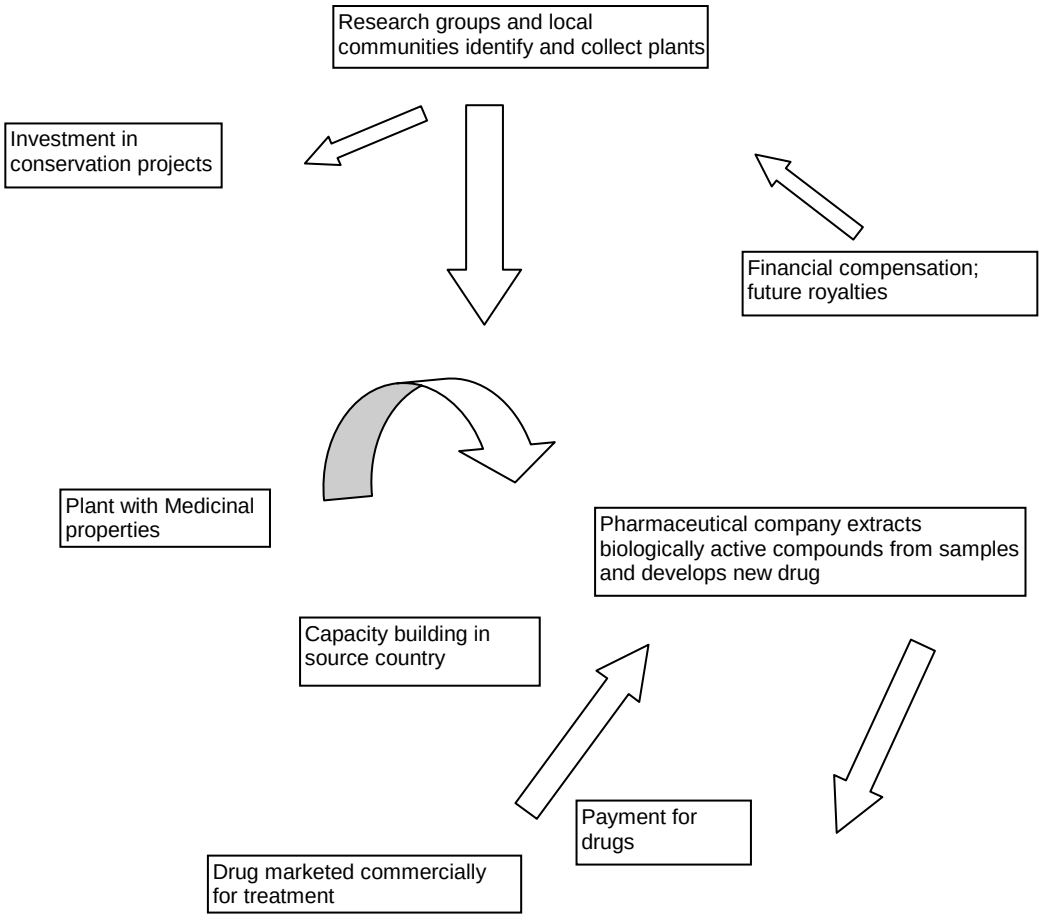
2. Stakeholders

It has long been understood that indigenous people of the world hold a vast storehouse of knowledge about the traditional uses of many native species of plants. In the past, many pharmaceutical and agricultural companies may have made use of this knowledge to identify source plants and extract compounds for analysis and development with little regard for the protection of intellectual property and with no provision made for equitable sharing of profits with those indigenous groups. New guidelines suggested as part of the ongoing talks to the CBD will incorporate the concept of an internationally recognized certificate of origin. This will provide a trail from the source country to the locale of the eventual commercial development of a product. These guidelines have provoked some concern among researchers in developed countries. As Matthew Jebb, Acting Director of the National Botanic Gardens in Dublin stated during negotiations at the Seventh Meeting of the Conference to the Parties of the Convention on

Biological Diversity in Kuala Lumpur, Malaysia, "It is a bitter pill to swallow, but the moral argument is uncontestable. We are reaping the legacy of more than 100 years of European domination" (Nature, 2004).

Bioprospecting activities are not limited to independent specialized firms but are also carried out by large multinational firms and by universities and scientific research centers. Typically, the overall stakeholders involved in bioprospecting arrangements are indigenous councils, multinational pharmaceutical companies, local private firms, local research institutions, environmental NGO's and others.

DIAGRAM 1
A SIMPLIFIED CYCLE OF BIOPROSPECTING BENEFITS

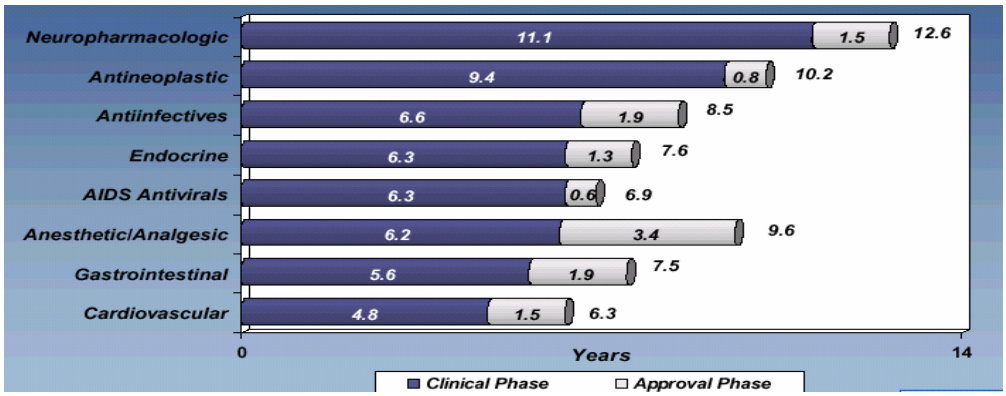


Source: Conservation Finance Alliance.

3. Challenges

The road to pharmaceutical product approval continues to be challenging. The product approval times are lengthy, costs are high and attrition rate of candidate drugs is high.

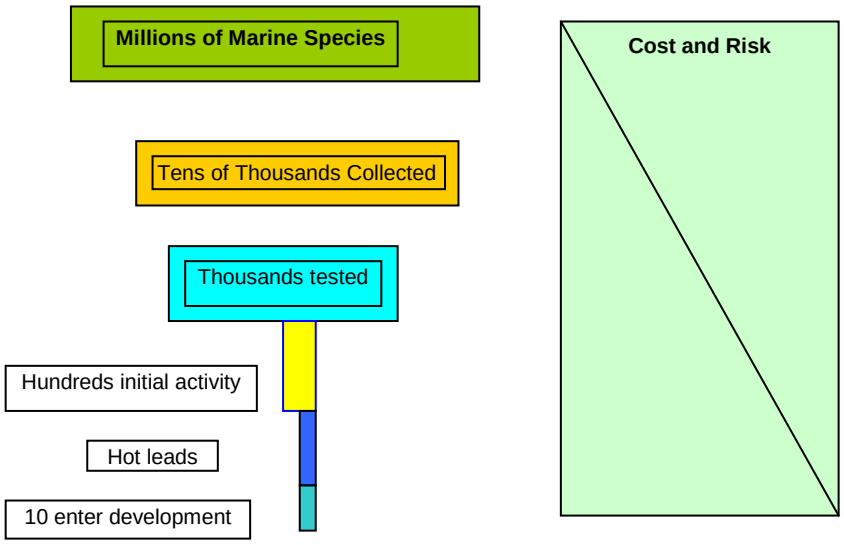
DIAGRAM 2
CLINICAL AND APPROVAL TIMES VARY ACROSS THERAPEUTIC CLASSES, 2002-04



Source: K. Kaitin, Tufts University, Center for the Study of Drug Development, 2005.

Improvements in the ability to isolate compounds from animals and plants have served to increase the interest of pharmaceutical and biotechnology firms in biodiversity regions in developing countries. An example of a US company involved in bioprospecting is the Diversa Corporation in San Diego, California. This company is involved in the rapid discovery and optimization of novel products from genes and gene pathways. Diversa focuses on the discovery, evolution, and production of commercially valuable molecules with pharmaceutical applications, such as optimized monoclonal antibodies and orally active drugs, as well as enzymes and small molecules with agricultural, chemical, and industrial applications. Diversa has bio-prospecting agreements in place in six countries. It has found new "thermophile" microbes in the hot springs of Yellowstone which is currently on hold due to litigation but is expected to continue. The company has collected bacteria from a whale carcass in the Pacific Ocean. Diversa has only catalogued about 10,000 microbial species, but the company's DNA libraries contain genes from nearly 2 million different strains of microorganisms including many from extreme environments. Diversa has had ongoing bio-prospecting programs in Costa Rica with the Institute of Biodiversity (INBio) and in Mexico with the Universidad Nacional Autónoma de México; it is negotiating agreements in Panama and Brazil. In Costa Rica, Diversa's INBio collaborators collected organisms from thermal spots like hot springs, mud pots and steam vents. They have examined insects that eat strange things like toxic plants. The guts of these insects are then extracted in order to find organisms that help the insects neutralize toxic chemicals.

DIAGRAM 3
ORDERS OF MAGNITUDE IN DRUG DISCOVERY IN EVANS, E.A.



Source: Australian Institute of Marine Sciences.

Technological advancements: In Bronwyn Parry's book *Trading the Genome* (Parry, 2004); she suggests that at the beginning of the 21st century there are interesting parallels between the evolution of information technology and biotechnology. Just as a user browsing on the Internet may download a song in an MP3 format, and may then take a digital copy and make infinite copies, remix it, blend it and pass it on to friends so too, biological material can now be stripped down to its genetic code and rendered into something else. The genetic, biological material becomes "transmissible, transformable" and can be manipulated to serve the needs of the researcher or end user. Parry suggests these new technologies will transform, indeed are already transforming man's relationship with the natural world.

Synthetic production of materials: Technological developments are beginning to release corporations from their dependence on *in situ* collecting. A direct consequence of advances in screening, synthesis and plant cell culture now allows for the extraction of genetic materials or biological compounds which can then be exploited in many ways. It opens the door for synthetic reproduction. In l988 only 12 percent of all plant-derived drugs could be reproduced using a process of synthesis but by the late 1990s it is estimated that more than 50% of them could be produced using these methods (Parry, 2004).

Taxol, the compound for fighting breast cancer which was first found in the bark of the Pacific Yew is now being produced from tissue culture. Thus, it is increasingly possible to rapidly generate viable quantities from small amounts of collected material. It is suggested that "the ability to secure biochemical compounds through processes of replication or recombination seriously undermines the viability of existing collecting projects".

Gene Banks: From l985 to l995 the National Cancer Institute entered into what was called an historic revival of collecting of biological samples. The NCI contracted with U.S. based botanical gardens which had relationships with similar organizations in developing countries to carry out collections in the field. Collections took place in over forty countries in what can only be

described as the first globalized, U.S. based biological collection program. Developments in the field of molecular biology and genetic engineering had radicalized the approach to drug design as had advances in automation which facilitated the development of high throughput screening techniques. At the same time technological developments allowed the NCI to test smaller quantities of material provided by smaller companies and universities. This provided impetus for botanical gardens, universities and research institutions to collect material for commercial evaluation or submit existing collections for testing (Parry, 2004).

However, the NCI responded to criticism which compared these collecting efforts to vestiges of the old biocolonialism. In an unprecedented move they set up formal agreements, a letter of intent which would govern the terms of access to and subsequent use of genetic and biochemical material. The original letter of intent evolved into a Memorandum of Agreement whereby long term compensation is secured through an agreement that requires that any "licensee of a drug produced from the material seek as its first source of supply, natural products available from the source country" subject to the negotiation of a mutually agreed fair price". In return the NCI maintains the right to patent all inventions developed under the agreement. The original letter of intent with its structure of short, medium and long-term compensation which provides for an up front collection fee, training, and a royalty on products has become the model for subsequent negotiations (Parry, 2004).

4. Organisms from extreme environments

Of special relevance to biodiversity-rich developing countries found in the tropical regions are those organisms that are able to survive under harsh or extreme conditions known as "extremophiles". The table below provides some examples of types of extremophiles and their applications.

TABLE 2
EXTREMAPHILES AND THEIR APPLICATIONS

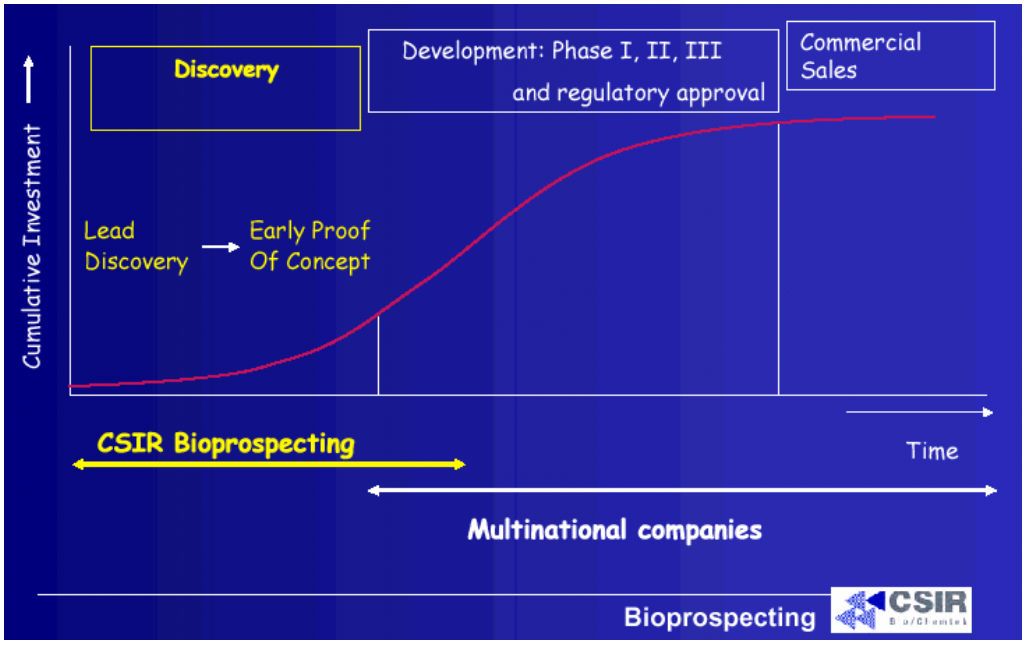
Thermophiles & Hyperthermophiles	Applications
DNA polymerases	DNA amplificatio-n by PCR
Lipases, pullulanases, and proteases	Detergents
Amylases	Baking and brewing
Xylanases	Paper bleaching
Halophiles	Applications
Bacteriorhodopsin	Optical switches and photocurrent generators
Lipids	Liposomes for drugs delivery and cosmetics
Compatible solutes e.g. Ectoin	Protein. DNA, and cell protectants
^(-Linoleic acid, ß-carotene, and cell extracts. e.g. Spirulina and Dunaliella	Health foods, dietary supplements. food colouring, and feedstock
Psychrophiles	**Applications**
Alkaline phosphatase	Molecular biology
Proteases, lipases, cellulases, and amylases	Detergents
Polyunsaturated fatty acids	Food additives, dietary supplements
Ice nucleating proteins	Artificial snow, food Industry e.g. Ice cream
Alkaliphiles & Acidophiles	**Applications**
Proteases, cellulases, lipases, and pullulanases	Detergents
Elastases, keritinases	Hide de-hairing
Cyclodextrins	Foodstuffs, chemicals, and pharmaceuticals
Acidophiles	Fine papers, waste treatement and de-gumming
Sulphur oxidizing acidophiles	Recovery of metals and de-sulphurication of coal
Acidophiles	Organic acids and solvents

Source: Malony, S. (2004). Extremophiles: Bioprospecting for antimicrobials. Antiviral Chemistry and Chemotherapy (as cited in Philip A. Read, Resources in Technology, The Technology Teacher, Jan. /Feb. 2005).

5. Myths and realities

A review of the current literature on the subject of bioprospecting reflects a wide variety of viewpoints with regard to the economic development returns from this activity. It is often the case that expectations for returns exceed the reality of actual products being brought to market. Although there continues to be much interest in pursuing targeted bioprospecting activities which can lead to significant business opportunities, there are also arguments which cite the long and expensive road to validation of research findings and product approval. With the introduction of new restrictions on access to genetic materials and other regulatory considerations the topic certainly warrants additional empirical information to guide all sides of these arguments.

DIAGRAM 4
DRUG DEVELOPMENT CYCLE



Source: CSIR, South Africa, Feb. 2005.

6. Bioprospecting and the Convention on Biological Diversity

General provisions of the CBD. As stated earlier in this report the Convention on Biological Diversity was first signed by participating parties at the Earth Summit in Rio de Janeiro, Brazil in 1992. The (CBD) recognizes state sovereignty over genetic resources. It also acknowledges the rights stemming from indigenous knowledge, specifying certain obligations in the area of access and benefit sharing. The general objectives of the CBD are to conserve biological diversity, enable sustainable use of its biodiversity resources and ensure the fair and equitable sharing of benefits arising from the utilization of genetic resources. The CBD allows national governments to regulate access to their natural resources, recognizing the rights of local communities to protect their traditional knowledge. Subsequent meetings of the parties have generated guidelines for obtaining prior informed consent and mutually agreed upon terms for access and benefit sharing involving both monetary and non-monetary resources.

6.1 Intellectual property rights and the CBD

The Convention on Biological Diversity (CBD) was the first formal effort to provide diversity-rich countries with the means to benefit significantly from the utilization of their bioresources. According to the provisions of the CDB national governments have the authority to control access to their genetic resources. Governments should provide for "the conservation, sustainable use, and equitable sharing of benefits from the commercial use of those resources" (CBD, 2005).

Article 2 of the CBD defines genetic resources as "genetic material of actual or potential value". It is the potential value of these extracts, as yet unknown, which has created so much expectation and is the source for anxiety bringing up old North-South issues. Echoes of colonialism

have surfaced where once again the rights of indigenous peoples who may use unknown traditional medicines seem once again pitted against large companies within the developed world which seek to take advantage of these resources.

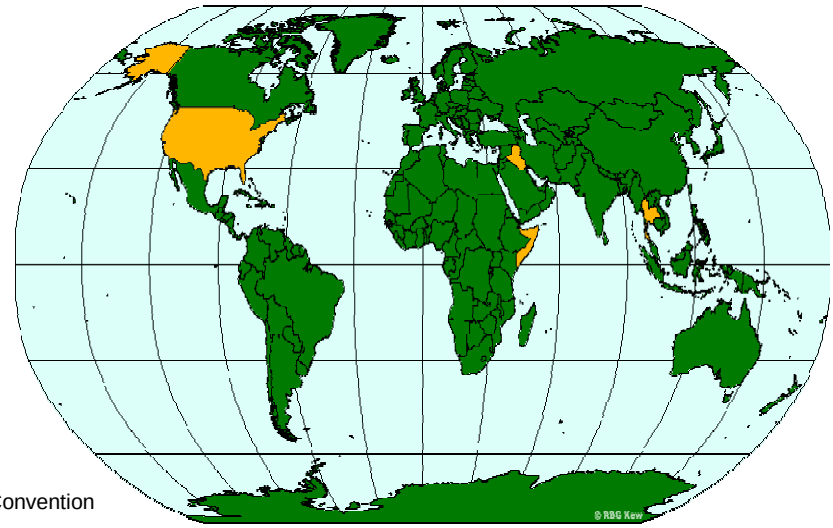
An important conflict has arisen between the CDB, which supports the sovereign rights of nations over their biological resources and the Agreement on Trade-Related Aspects of Intellectual Property Rights (the "TRIPs agreement"), which supports private rights to intellectual property. As a result of this conflict national attempts to regulate bioprospecting have been largely unsuccessful in that they do not adequately address the complexities of drug R&D developed from genetic resources. The creation of bioprospecting frameworks at national levels has been further complicated by negotiations including an international regime on access and benefit sharing as well as negotiations about the inter-relationship between traditional resources, genetic resources and intellectual property rights. Legal uncertainties and weak regulatory systems in many developing countries have prevented many pharmaceutical companies from investing in bioprospecting. The result has been largely that due to the uncertainties of the proposed arrangements and legal wrangling, many drug countries have shied away from using natural sources and are exploring other avenues for R&D development (Sittenfeld (1996) and Sittenfeld and Lovejoy (1999)).

According to Padmashree Sampath, the CBD provides a good starting point for constructive dialog on the roles and responsibilities of users and providers in bioprospecting. She suggests that two of the most significant articles under consideration are numbers 15 and 8(j). Article 15 recognizes the rights of national governments to regulate access to genetic resources situated within their territories. Article 8(j) recognizes the rights of indigenous communities in relation to their traditional knowledge and practices (Sampath, 2005).

At the Seventh Meeting of the Conference of the Parties to the Convention on Biological Diversity (CBD) in Kuala Lumpur, Malaysia, representatives agreed on guidelines to be prepared in time for approval at the next conference in Rio de Janeiro, Brazil in 2006. The guidelines are set to incorporate the idea of an internationally recognized certificate of origin, as a kind of passport for any scientific discovery. This will allow the source country and developer to follow the trail from its place of origin to its commercial exploitation (Nature, 2005).

The Convention on Biological Diversity is a landmark international treaty with the objectives of conservation of biodiversity, sustainable use and fair and equitable sharing of genetic resources. Prior to the implementation of the CBD, there were a number of famous cases of the discovery of biotic material in developing countries which were eventually turned into blockbuster drugs but which provided no return to the country of origin. In a post CBD world, access and benefit sharing arrangements afford the most equitable arrangement to return not only monies to those countries but also require conservation, capacity building and often include training for local researchers.

DIAGRAM 5
PARTIES TO THE CONVENTION ON BIOLOGICAL DIVERSITY

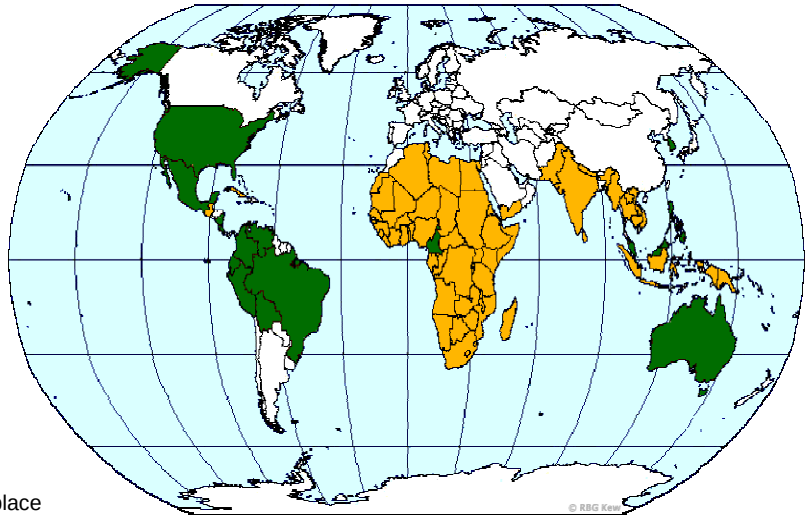


Party to the Convention
Non Party to the Convention

Source: Adapted from CBD for Botantists Royal Botanical Gardens, Kew, U.K., 2004.

When the CBD was first presented in Rio de Janeiro, Brazil in 1992, more than 150 countries showed their support for its provisions by signing it. The CBD officially came into force in December 1993, 90 days after it had been formally accepted by 30 countries through a process of ratification. These 30 countries then became "Parties" to the CBD. The CBD has been ratified by more countries worldwide than any previous international treaty. At present there are 186 countries plus the European Union which have signed on to the CBD. Notably only seven countries have not ratified the convention- they are Brunei, Andorra, East Timor, Iraq the Vatican and the United States.

DIAGRAM 6
NATIONAL LEGISLATION ON ACCESS AND BENEFIT-SHARING



Legislation in place
Planning legislation

Source: Adapted from CBD for Botantists Royal Botanical Gardens, Kew, U.K., 2004.

The CBD is comprehensive in covering all aspects of biological diversity including ecosystems and habitats, species indeed the genome as a whole. But even as nations around the world have signed on, it continues to be a changing, evolving body of international law. Through the work of its committee, the Subsidiary Body on Scientific, Technical and Technological Advice (SBSTTA) and the biennial meetings of the Conference of the Parties (COP) new recommendations are being proposed and adopted. To date there have been some 180 COP decisions and the adoption of a Global Taxonomy Initiative, Guiding Principles on Invasive Alien Specials and a Global Strategy for Plant Conservation (ten Kate , 2004).

The treaty offers a framework for research centers, companies and traditional communities to negotiate around shared goals of conserving the biological diversity of the planet. Indeed, as was noted in the ten year overview of the CBD, since coming into force more than 100 countries have participated in comprehensive planning initiative for natural resources management.

The influence of the Convention is already being felt in communities across the globe by the implementation of new policies and support for scientific research. A key outcome is the regulation of access to genetic resources. For example, even though the terms of the collaboration between the National Institute of Biodiversity (INBio) in Costa Rica and the pharmaceutical firm Merck & Co. were decided upon for took place before the CBD came into force, it is likely that intense discussions in preparation for the Convention were already in motion and thus informed this agreement. The INBio-Merck agreement represents what many consider a model that would serve for future collaboration. Among the hallmarks of this agreement were strict regulations for benefit sharing, technology transfer and capacity building, including a requirement that much of the research be conducted in Costa Rica. These outcomes represent what countries that ratified the CBD would wish for their own institutions and constituencies.

The Cartagena Protocol on Biosafety adopted in January 2000 was proposed to address potential risks posed by living modified organisms and to ensure an adequate level of protection in the transfer, handling and use of living modified organisms resulting from modern biotechnology that might have adverse effects on biological diversity, It also takes into consideration the risks of those organisms to human health. The Protocol promises to make a contribution to promoting technology transfer by allowing countries in the developing world to have access to information from the biotechnology industry. The Protocol entered into force on 11 September 2003, ninety days after receipt of the 50th instrument of ratification. As of July 2005, 124 instruments of ratification or accession have been deposited with the UN Secretary-General.

CBD and TRIPS: There is continuing discussion about the conflicting provisions of the Trade-Related Aspects of Intellectual Property Rights (TRIPs) Agreement of the World Trade Organization (WTO) and the CBD. The concerns relate to issues of the control, custody and conservation of the world's biological resources. Specifically, it has been argued that one of the TRIPS articles relating to the patentability of living organisms may undermine goals and principles of the CBD which recognizes the rights indigenous populations as custodians of biological stock and associated traditional knowledge. That is while TRIPS recognizes individual, private property rights in relation to processes and applications of said organisms, CBD recognizes the collective rights of local communities on the same. The chart below highlights some of these issues and differences.

TABLE 3
CBD VS. TRIPS

Main CBD issues	Conservation of biodiversity Sustainable use of its components Fair and equitable sharing of benefits on derived products Protection of traditional access to genetic resources and technology
Main TRIPS issues	Reduce distortion and impediments to international trade Promote effective and adequate protection of intellectual property rights (IPR), including for plant varieties and other genetic innovations Ensure that measures and procedures to enforce IPR do not themselves become barriers to legitimate trade
Potential Conflicts	TRIPS asserts IPR protection on life forms; CBD asserts national sovereignty and right to prohibit such protection CBD promotes equitably shared benefits from use of biological resources and protection of traditional knowledge; TRIPS promotes private appropriation of benefits with no mechanism for acknowledging role of traditional knowledge from which industrial applications may derive.
Potential Resolutions	Article 1 of TRIPS provides some flexibility, allowing domestic law to exceed minimum protection standards--a provision that could allow member nations to enact legislation to protect traditional knowledge Article 27.2 of TRIPS allows for the exclusion from patentability based on public order or morality Article 27.3b of TRIPS allows for the development of unique IPR protection systems for plants, animals, and essentially biological processes, creating an opportunity to develop alternative IPR regimes appropriate to the needs and conditions of traditional communities

Source: The Global Biodiversity Institute, 2000.

Under the terms of the CBD, the Conference of the Parties is the governing body of the Convention. This body advances implementation of the Convention through decisions it takes at alternating meetings which take place in different areas of the world. The intergovernmental meeting which took place during COP VI in Bonn, Germany, in October, 2001 prepared a draft agreement hence known as the “Bonn Guidelines”. It was adopted in The Hague in April 2002 and identified steps in the process to provide access to genetic resources and fair and equitable benefit sharing. The Guidelines have been acknowledged to be a key step in the process of implementing those provisions. These guidelines continue to be reviewed and refined and, while voluntary, should assist governments, stakeholders and interested others in setting up necessary legislative and administrative policies in regards to access and benefit-sharing agreements and negotiation of contracts.

7. Bioprospecting in selected countries and regions

Just as certain nations are promoting biodiversity conservation measures, they are also taking initiatives designed to enable industrial activities in the sustainable use of biodiversity resources. Some governments in biodiversity-rich countries are increasing their support for research and development activities and providing incentives for private sector investment in the creation of businesses and related commercial bioprospecting. The following pages describe such initiatives in Australia, South Africa, and Malaysia as well as activity in the United States. Also included in this section are observations on current discussions relating to bioprospecting in Antarctica.

7.1 Bioprospecting in the US

Discovery of TAQ and the Yellowstone Diversa CRADA

The discovery of a thermophilic bacteria which had been legally collected in the boiling pools of Yellowstone National Park in the 1960's and which was subsequently deposited in the American Type Culture Collection (ATCC) database for future research holds a lesson for those concerned about the equitable sharing of benefits (ABS). The bacteria known as Taq which was used to develop the blockbuster technique PCR is an excellent example of the potential riches which many consider lying within the world's vast untapped biodiversity. Moreover, it illustrates one of the many caveats inherent in any bioprospecting endeavor. Because no agreements were in place with the National Park Service at the time of collection, Yellowstone did not benefit directly from the commercial success of the Taq polymerase. Thus even within a developed country which maintains vigorous legal protection for its natural resources there have been instances where benefits did not return to the source.

The 1980's saw an new increase in the search to collect species fueled in part by the increased success of the polymerase chain reaction (PCR) an important technique in modern molecular biology (Doremus, 2004) This technique permits the identification and manipulation of minute DNA molecules which can then be replicated into unlimited quantities. This technique was developed by Kary Mullis who subsequently received the Nobel Prize in chemistry for this discovery. PCR was developed by using the Taq polymerase enzyme collected some twenty years earlier and available in the ATTC bank. Mullis, who worked for the CETUS Corporation subsequently patented the technique and the company sold the rights to the process to Hoffman-La Roche laboratories for $300 million. Taq polymerase and PCR were a huge commercial success. It is estimated that patents on Taq polymerase continue to return millions of dollars each year to the original owners of the patent.

In the mid 1990's Yellowstone National Park undertook a plan to implement benefits-sharing which would allow park managers to negotiate Cooperative Research and Development Agreements (CRADAs) under the Federal Technology Transfer Act as a legal approach to implement benefits-sharing agreements and enhance resource conservation. Under the CRADA a non-federal scientist or company is required to share reasonable benefits with the park. Some biotech companies reacted negatively stating that the government already benefited from commercial biotechnology by taxing corporate profits. However, in 1997, the Diversa Corporation which had previous contracting experiences in Costa Rica entered into a CRADA with Yellowstone National Park to commercialize thermophiles. Under this agreement, any revenues accrued could be retained by the national park instead of being sent to the U.S. Treasury. The CRADA provided for the systematic sampling of habitats in the park, including the thermal areas. This sampling was to be conducted with a scientific collection permit and subject to park regulations. The CRADA is non exclusive in that Yellowstone may also enter into contracts with other biotech companies. In l998 a legal challenge was issued by three small non profit groups charging procedural claims and eventually the CRADA was suspended pending the requirement to conduct an Environmental Impact Study. Because the agreement was blocked for many years through litigation, it is too early to tell where discovery may lead. Most of the potential bioprospecting in national parks is currently related to the study of microorganisms which can live almost everywhere, including the thermal pools of Yellowstone National Park.

Under the 1998 National Parks Omnibus Act provision is made for benefits sharing agreements "between researchers, their institutions or companies" and the National Park Service but which also return benefits to the parks if research yields commercially viable products (National Park Service Website, 2005).

It is understandable that the National Park Service would wish to benefit from the potential economic riches which may be located in Yellowstone's biotic resources, but the challenge as was demonstrated in subsequent litigation was around a lack of public discussion of the issues which marked concerns about public resources becoming available to privatization. Simply put, as long as U.S. law allows patenting of a gene or protein which has been isolated from its natural source it will probably be unlikely to keep private organizations from making a profit without stifling scientific research. The discussion about the limits to privatization of organisms discovered within a national park in the U.S. or in any of the megadiverse sites around the world continues to present a dilemma. It has been suggested that researchers should make genetic information freely available to the public or agreements could forbid a patent on a gene, protein or specimen derived from a public park. This approach would be considered more consistent with conservation and equitable benefit sharing (Doremus, 2004).

7.2 Bioprospecting in Australia

Major institutions in Australia are conducting research involving bioprospecting. The Australian Museum (2003) reports that the Pharmaceutical Research Institute at Griffith University in Queensland is researching coastal marine organisms and rainforest plants from Queensland. This Institute is concentrating on products with potential therapeutic value in the cardiovascular, gastrointestinal and respiratory fields. Additionally, the Museum reports that the Key Centre for Biodiversity and Bioresources at Sydney's Macquarie University is studying certain species of native ants for purposes of looking for new sources of compounds with antibiotic properties.

The Commonwealth of Australia passed the Environment Protection and Biodiversity Conservation Act (EPBC)in 1999 to 'provide for the control of access to biological resources in Commonwealth areas'. Regulations under the EPBC Act require those seeking to develop natural resources to secure an access permit and provide a benefit-sharing contract. The Australian government developed an Inquiry that serves as the primary tool of Environment Australia's Access Work Program under Biotechnology Australia. A key objective of the Access Work Program was to offer a consistent system of inquiry for those seeking access to biological resources.

In September 2001, the Australian Minister for the Environment and Heritage, announced the release of a scheme to regulate access to biological resources in Commonwealth areas. This scheme supports the Commonwealth of Australia's commitment to a National Biotechnology Strategy which is to:

- promote the conservation of biological resources through their sustainable use;
- ensure that the Australian community shares in the social and economic benefits from their use;
- recognize, protect and value the special ecological knowledge of Indigenous people; and
- provide certainty to industry and researchers seeking access to resources while minimizing cost.

Under the recommendations of the Inquiry, regulations require a party seeking access to biological resources in Commonwealth areas to apply for an access permit from the Minister for the Environment and Heritage. The applicant will be required to negotiate with the holder (or owner) of the biological resources a *benefit-sharing contract* which covers the commercial and other aspects of the agreement inlcuding payments, up front, royalties and protection of Indigenous knowledge. It is recommended the contract be developed and agreed by governments, industry, Indigenous organisations and other stakeholders.

An Indigenous Advisory Committee (formed under the EPBC Act) is consulted on development of regulations taking into account the significance of Indigenous peoples' knowledge of land management, conservation and sustainable use of biodiversity' (Commonwealth of Australia, *Access to Biological Resources*. 2002).

7.3 Bioprospecting in South Africa

The "Bioprospecting Vision for South Africa" states that the country is "one of only few countries richly blessed with exceptional plant biodiversity, a long history of traditional use of medicinal plants and the scientific research infrastructure to add further value to these national assets." It further states that bioprospecting activities can contribute to the creation of economic and social benefits for the nation and for the region as a whole based on both its biodiversity and its indigenous knowledge.

South Africa passed The Biodiversity Act in May 2004 which provides for the management and conservation of South Africa's biodiversity. This new law covers biodiversity planning and monitoring, protection of threatened ecosystems, species control, management of alien and invasive species, and regulates bioprospecting activities, permits and addresses the issue of fair and equitable benefit-sharing. The Act also established the South African National Biodiversity Institute (SANBI).

Benefit–sharing in South Africa has come into focus as an important issue in order to justify conservation as a legitimate use for the land. The term has come to refer to the relationship of commercial use of biodiversity, generally among large multinational companies in the North who are provided genetic resources by in large from countries in the South. Because of South Africa's painful history of injustice including dispossession of members of the black community whose land was later designated for conservation, these injustices have resulted in the perception within South African that biodiversity conservation largely serves more privileged members of society and is not relevant to the larger needs of people (Wynberg, 2001).

According to Marthinus Horak, Manager of the Bioprospecting Programme of the Council for Scientific and Industrial Research (CSIR) one of the largest scientific and technological research organizations in Africa, South Africa is home to nearly 10% of all plants which make up the temperate flora in the world, many of which have been used for the treatment and prevention of diseases by traditional healers. The CSIR has embarked on a major bioprospecting project with the purpose of developing medicines based on some 24,000 indigenous plants.

CSIR signed a licensing agreement for further development and commercialization of a product P57 which had been developed from Hoodia, a succulent plant long used by indigenous peoples to alleviate hunger and thirst. CSIR made its original agreement with Phytopharm a company which specializes in the development of phytomedicines. Subsequently Phytopharm turned the compound over to Pfizer, a major U.S. pharmaceutical company for commercialization. CSIR will receive "milestone payments" related to the success of "P57" in clinical trials. P57 is being developed into a potential anti-obesity treatment.

Several years ago, the CSIR came to the realization that it held forty years of bioprospecting knowledge within the walls of its research facility which might be used to provide economic and social benefits for South Africa. In 2004, they signed benefit-sharing agreements with owners of Indigenous Knowledge (San Council and Traditional Healer Trust). CSIR entered into an agreement with the San people to discover more about the medicinal uses of traditional plants of the Kalahari. They also signed a bioprospecting agreement with Namibia in 2005.

BOX 2
BIOPROSPECTING POLICY IN SOUTH AFRICA – SETTING STANDARDS FOR BEST PRACTICE

- What is the environmental impact of collecting material and how has biodiversity? conservation been strengthened by the project?
- Was the prior informed consent of communities or landowners obtained / Will the prior informed consent of communities be obtained?
- How was consent from government obtained?
- How has the reconstruct ion and development of South Africa been promoted?
- How has economic development been promoted in marginalized parts of the country?
- Who are the intended beneficiaries of the project?
- What benefits have / will holders of traditional knowledge obtained from the project?
- What mechanisms exist to disburse funds to beneficiaries?
- What initiatives exist to ensure collaboration with other local research institutions?
- To whom have intellectual property rights for intended products been conferred?
- How has South Africa's science and technology capacity been enhanced by the project?

Source: Wynberg, Rachel from: "Benefit-Sharing in South Africa: Fact or Fiction?".

On another front, the National Biotechnology Institute maintains an Ethnobotany Program which is the central research area on the traditional uses of South Africa's plants including their conservation, sustainable use and development. A consortium of scientific institutes and universities which make up the South Africa 's Novel Drug Development Platform, are supporting bioprospecting of medicinal plants with particular interest in treating asthma, allergies, malaria, tuberculosis and HIV. With more than 200,000 self-reported "traditional healers" in South Africa, scientific researchers are well positioned to avail themselves of Indigenous knowledge systems (IKS) in the search for cures to many of the world's diseases.

7.4 Bioprospecting in Malaysia

Malaysia, which is one of the Megadiverse countries has strengthened the Sarawak Biodiversity Access, Collection and Research Regulation of 1998 in 2001. It now requires an Ethnobiological Research Permit for activities which involve collection of local biodiversity. Previous Malaysian laws, notably the Forestry Act of l984 and Protection of Wildlife Act did not go far enough to protect biological resources from potential biopiracy. At present the Malaysian government is in the process of passing an Access and Benefit Sharing Bill which will provide for equitable sharing of benefits and protect biological resources. When enacted, the ABS bill will require permits from researchers who wish to be involved in bioprospecting in Malaysia. Until this bill is enacted, Malaysia is using the "Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization" which is part of the CBD.

On another front, the Forest Research Institute of Malaysia (FRIM) has entered into a Memorandum of Understanding with Nimura, a Japanese genetic engineering firm. The joint venture will ensure benefit-sharing through a process whereby Japanese scientists working in local laboratories are required to leave a "copy" of every identified sample collected in Malyasia. Nimura is required to provide FRIM royalties for any "novel compounds". FRIM has been working with Malaysian universities since 2002 and has registered 300 native species with their traditional uses and is growing another 200 of these species in their arboretum.

Another joint venture between the Malaysia's TropBio Research and Fujisawa Pharmaceuticals, Japan's second largest pharmaceutical company focuses on soil bioprospecting. Soil samples are collected in Malaysia but Fujisawa is providing training for Malaysians thus locals benefit from acquiring new skills as well as employment. The scientific research community also benefits as part of an economic development strategy where local researchers have the opportunity to increase their skills through education and training directly linked to bioprospecting activities (Nature, 2004).

7.5 Bioprospecting in Antarctica

At the bottom of the world, the vast continent of Antarctica covers the South Pole with a permanent shield of snow and ice. Marked by the most extreme temperatures, the ice sheet is also subject to the strongest winds on earth. And yet, in those frigid seas and in the very ice itself life is teeming. Most of the discovery in Antarctica has taken place within the past one hundred years. In the middle of the last century a multinational geophysical station was set up by twelve countries, nine of which have asserted some form of territorial claim on the continent. However, in the interest of scientific research these countries have put aside their political and legal differences and signed an agreement which provided guidelines for future activities. In l959 Argentina, Australia, Belgium, Chile, France, Japan, New Zealand, Norway, South Africa, United Kingdom, United States and Russia signed an agreement whereby those countries which are active in Antarctica must consult each other around uses of the whole continent. Aside from the stipulation that no military use may be made of the continent, key provisions require scientific research to be freely exchanged among these countries. Since entering into force in 1961, the treaty has been recognized as an extremely successful international agreement. In l964, these same countries signed *Agreed Measures for the Conservation of Antarctic Fauna and Flora* under which a designated "Specially Protected Area" is accorded singular protection in order to preserve the unique natural ecological system. In 1991 a subsequent *Protocol on Environmental Protection to the Antarctic Treaty* enhanced protection of the Antarctic environment and is dependent ecosystems.

On the eve of the 7th Conference of Parties to the CBC, the UNU-IAS released a report which reviewed bioprospecting in the polar region. **The International Regime for Bioprospecting: Existing Policies and Emerging Issues for Antarctica**, was undertaken to support global biodiplomacy. For many years The Scientific Committee on Antarctic Research (SCAR) and the Antarctic Treaty Consultative Meeting (ATCM) has guided scientific research. More recently they have begun to address the issue of bioprospecting. Most of the current research in Antarctica has been carried out by universities, research centers and pharmaceutical companies. Much of the interest in Antarctica stems from a lack of knowledge about the continent's vast biota and the understanding that extreme cold, aridity and salinity of the water on the continent present favorable conditions which may well yield as yet undiscovered species. For example, a glycoprotein which keeps a specific Antarctic fish from freezing in the subzero waters may well have commercial value. This compound is being considered for use in everything from extending the life of frozen food to freezing tissues for surgery. Such discoveries have propelled an investigative relationship between the University of Tasmania and an Australian pharmaceutical company to screen some 1000 samples of Antarctic microbial samples for antibiotics. And. another Australian biosciences laboratory, Cerylid is working with more than 600,000 samples including plants and microorganisms.

As a mark of worldwide interest in Antarctica, according to the patent office of the European Union, sixty-two patents relating to Antarctic biodiversity have been issued and another ninety-two patents referencing Antarctica have been registered with the U.S. Patent Office. Although the process from discovery to development is known to take a long time, it is reported that there has been great expectation within the private sector which has provided more than one million (U.S.)

dollars in funding since l997 for the promise to discover useful genetic resources which survive in the harsh clime of the polar region (UNU/IAS Report, 2003).

8. Global themes and issues

The following sections address certain themes and issues relevant to ongoing policy discussions on commercial bioprospecting. These include access and benefit sharing, diversification of benefits, biopiracy and prior informed consent.

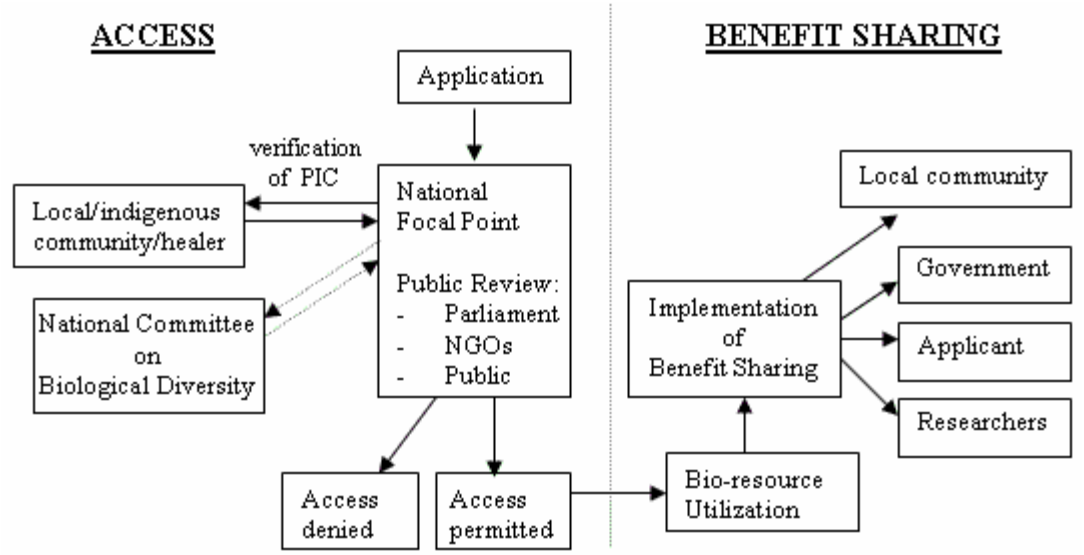
8.1 Access and benefit sharing

Since its creation in 1992, the CBD has enabled and encouraged individual countries to develop their own policies and legislation for access and benefit sharing (ABS). Although the CBD was developed as a response to a renewed interest in bioresources and as a means to ensure the equitable sharing of benefits resulting from allowing access to genetic resources, the CBD has met with limited success. In 2002, at the Johannesburg World Summit for Sustainable Development, renewed interest was given to develop an international framework on ABS (Parry, B. 2004).

Diversification of benefits: As bioprospecting arrangements are negotiated, participating parties continue to explore both monetary and non-monetary benefits in addition to the initial fees and traditional royalties. These include technology transfer, capacity building and scientific training, community development projects and others. Similarly there is room to explore additional areas of collaboration and international program development of mutual benefit to the scientific and business communities.

Biopiracy and informed prior consent: As bioprospecting activities are often carried out by bio-pharmaceutical firms from developed countries in less developed countries with rich biological diversity and economically disadvantaged populations, the arrangements can often lead to accusations of unfair exploitation and “biological piracy” or “biopiracy”. However, accounts and accusations of biopiracy are not always accurate and consistent. To be sure, there are certainly documented cases of situations where compounds have been taken from the host country without either proper recognition or compensation. However, it is also true that there are situations when seemingly all of the steps have been taken by the bioprospecting groups and yet questions arise with regard to the level of informed consent and the legitimacy of the particular local agents involved. There continues to be a problem of clarity and consistency in the local laws and regulations. In the case of the Maya ICBG project described elsewhere in this report, Cori Hayden states that “Activists voiced concern about inadequate processes of consent, about the criteria through which participants would be included, about and the meager returns on offer” (Hayden, 2005). Related to the point above is the frequent absence of national laws providing clear guidance as to who and what institutions can represent local interests.

DIAGRAM 7
ACCESS AND BENEFIT SHARING CONCEPT



Source: Adapted from L. Wijayanti.

Despite the ongoing efforts of host nations to facilitate access, sharing of benefits and biodiversity conservation, experiences to date have demonstrated that many of the prevailing regulatory regimes have instead constituted roadblocks to arrangements and deals that would be of value to all parties. One researcher from the United Nations University, P.G. Sampath, has recently authored a book titled Regulating Bioprospecting (2005) in which she discusses approaches that developing countries might consider to encourage fair and sustainable use of their biological resources through appropriate regulation and building of research capacity. Although all of the provisions required to facilitate agreements and working arrangements for the large pharmaceutical companies operating in biodiverse countries are in place, Sampath observes that most bioprospecting partnerships set up since the Convention came into force in 1993 have failed to produce the expected drugs. She states that bureaucracy, legal uncertainties and weak regulatory frameworks in developing countries have made some pharmaceutical companies hesitant to invest in bioprospecting. A recent publication from the World Conservation Union IUCN Environmental Law Program Accessing Biodiversity and Sharing the Benefits: Lessons from Implementing the CBD (2004) provides a comparative analysis of the laws and policies of many countries that signed the CBD including in-depth profiles on Costa Rica, Chile, Colombia, and Mexico.

The following chart lists some of the countries that have either adopted or are developing ABS policies and legislation.

BOX 3
COUNTRIES WITH ABS POLICIES AND/OR LEGISLATION

The Andean Community (Bolivia, Colombia, Ecuador, Peru and Venezuela). The Decision 391 "Common Regimen on Access to Genetic Resources"

The Model Law of the Organization of African Unity (53 countries).

The ASEAN Framework Agreement on Access to Genetic Resources (10 countries).

Australia. The States of Western Australia and Queensland are undergoing modifications of their pre-existing legislation on conservation and management of natural resources.

Brazil. At the federal level, the Provisional Measure No 2186 from August 23rd, 20017 and at the state level, the States of Amapa and Acre.

Costa Rica. The Biodiversity Law of Costa Rica and the Draft Regulations known as the Access Rules to Genetic and Biochemical Resources which is pending publication.

Malaysia-Sarawak and Sabath. At the national level there is a Draft Law on Access to Genetic Resources.

Philippines. Executive Order 247 of 1995 and the Administrative Order No.96-20, of June 21, 1996.

India, Biodiversity Bill of 2002.

Bhutan, Biodiversity Act of 2003.

Argentina, draft legislation on Access to Genetic Resources of Biological Diversity of 2002.

Bangladesh, Biodiversity and Community Knowledge Protection Act of September 1998.

Cameroon, Forestry Law of 1994 and Framework Law for Environmental Management of 1996.

China (Protection of Wildlife Law of 1989, the Regulations on Seed Management, 1991, etc.)._

Cuba, Law-Decree on access to genetic resources, version of 2003.

El Salvador, General Environment Law of 1996 (art. 66 on access to genetic resources) and draft regulation on access to the genetic and biochemical resources associated to wildlife, version 2002.

Ecuador, Biodiversity Law of 1996. A broader Biodiversity Law is under discussion.

Eritrea, Proclamation on the Conservation of Biological Diversity of 1996 (arts. 46 and following] on access to genetic resources).

Fiji, Sustainable Development Draft Bill of 1996 (Section 249 and ss.) on biodiversity prospecting.

Gambia, Act for the Control and Management of the Environment of 1994 (section 34 and 35 on access to genetic resources).

Indonesia, Government regulation No 44 concerning plant seed management of 1995. A Genetic Resources Management Law is expected to be submitted to the Parliament in 2005.

Italy, Regional Law of 1995, Protection of the Genetic Patrimony of the Species of Indigenous Flora autochthonous of Veneto.

Kenya, Environment and Management Conservation Bill of 1999 (Section 53).

Lebanon, Draft Biodiversity Law of 2003.

Malawi, General guidelines for the collection of genetic materials in Malawi by foreigners of 1996

Mexico, General Law of Ecological Equilibrium and Environmental Protection of 1996 (arts 87 bis and 87 bis 1). Forestry Law, February 2003 (arts 101-106).

Nicaragua, General Environmental Law of 1996 (arts 61-64 on access to genetic resources). A draft biodiversity Law has been prepared.

Nigeria, National Park Service Decree of 1999.

Pakistan, Draft legislation on access to biological resources and community rights.

Panama, General Law of the Environment No 41 of 1998 (art 72 on access to genetic resources).

Peru, Law on Conservation and Sustainable Use of Biological Diversity No 26839 of

1997 (section VII Genetic Resources) and Supreme Decree No 068-2001 Regulation of the Law of 2001.

Portugal, Decree-law No 118 of 2002 on the register and protection of traditional varieties.

Samoa, Department of Land, Surveys and the Environment, conditions for access and benefit sharing of Samoan biological resources of 2000

Senegal, Ministerial Agreement for the creation of the National Committee of Phytogenetic Resources of 1996.

South Africa, White Paper on conservation and sustainable use of biological diversity and the National Environmental Management: Biodiversity Bill

The Seychelles, Draft Environment Protection (Biodiversity Authority) Order of 1995.

Thailand, Prime Minister Regulation on the Conservation and Utilization of Biological Diversity B.E.2543 of 2000.

Uganda, National Environment Statute of 1995 (art 45 on access to genetic resources).

United States of America (permit system used by the National Parks authorities, Code of Federal Regulations, Title 36, section 2.5,).

Source: IUCN Workshops, 2004.

II. Bioprospecting experiences in Latin America and the Caribbean

1. General overview

There continues to be some variation in the level of bioprospecting activity among the countries of Latin America and the Caribbean. Accordingly, there are appreciable differences in the scope and extent of legislative provisions which have been adopted by the respective countries.

As described in Box 1 shown earlier in this report, the countries of the Andean Community (Bolivia, Colombia, Ecuador, Peru and Venezuela) have adopted Decision 391 "Common Regimen on Access to Genetic Resources". Additionally, Ecuador has the Biodiversity Law of 1996 and a broader Biodiversity Law is under discussion. Peru also has a Law on Conservation and Sustainable Use of Biological Diversity No 26839 of 1997 and Supreme Decree No 068-2001 Regulation of the Law of 2001.

Brazil has the Provisional Measure No 2186 of 2001 at the federal level, and, at the state level, Amapa and Acre have their own legislation. Costa Rica has the Biodiversity Law of Costa Rica and the Draft Regulations known as the Access Rules to Genetic and Biochemical Resources. Argentina has draft legislation on Access to Genetic Resources of Biological Diversity of 2002 and Cuba the Law-Decree on access to genetic resources, version of 2003. El Salvador has the General Environment Law of 1996 as well as draft regulation on access to the genetic and biochemical resources associated to wildlife of 2002. Mexico has the General Law of Ecological

Equilibrium and Environmental Protection of 1996 and the Forestry Law of 2003. Nicaragua has the General Environmental Law of 1996 and a draft biodiversity Law has been prepared. Panama has the General Law of the Environment No 41 of 1998 with a specific article on access to genetic resources.

Although Costa Rica is recognized for having put together one of the first viable access and benefit sharing agreements in the early 90's with the Merck InBio contract, Brazil is now clearly at the forefront of developing a wide variety of legislative provisions designed to regulate access and ensure equitable distribution of benefits. However, even in countries where legislation is already in place, many enforcement challenges remain and the track record has not necessarily been consistent. In the case of Brazil, regulations have recently been relaxed for academic researchers but the enforcement measures for commercial endeavors have been tightened. The Brazilian government suspended a contractual arrangement that the Swiss corporation Novartis Pharma had entered into with the organization "BioAmazonia" for research into 10,000 microorganisms. Novartis had agreed to pay up to 4 million dollars over three years. Although the Bioamazonia organization includes governmental, scientific and business institutions, it was argued that the proper authorities in the Ministry of the Environment were not consulted. The Brazilian bioprospecting firm Extracta (which has over 4,500 medicinal plants in its library and is profiled later in this report) has also seen the need to contend with significant regulatory hurdles in its compliance with the Genetic Patrimony Management Council CGEN (*Conselho de Gestão do Patrimônio Genético*) which controls plant research, and Brazil's intellectual-property law. According to a recent article in Newsweek, the research work at Extracta has greatly reduced its bioprospecting activities (Newsweek April 11/18, 2005). Brazil has created the Molecular Ecology Program for the Sustainable Use of Biodiversity of the Amazon.

In Panama, it is encouraging to see that the public policy initiatives relating to bioprospecting have benefited from the efforts of the programs related to the International Cooperative Biodiversity Groups (ICBG). These programs have placed primary emphasis on capacity-building in the country to carry out value added activities in connection with the extraction, isolation, characterization and processing of candidate compounds.

While Mexico has had at least two recent high-profile situations where well-intentioned bioprospecting arrangements have been cancelled, there are still elements within the governmental, academic and industrial sectors that are working toward ways to institute effective and equitable arrangements for all parties involved. An ICBG-sponsored effort involving the University of Georgia and local groups in Chiapas was undermined by claims of "biopiracy" and uninformed consent. Similarly, there was also a failed agreement between the San Diego-based company Diversa and the National University (UNAM) which questioned the legitimacy of UNAM to speak for the traditional knowledge sources involved. Both of these experiences in Mexico illustrate the importance of having clear and consistent legislation in place.

2. Legislative initiatives

It is relevant to consider various existing and proposed legislative initiatives in selected Latin American countries which are intended to provide a guiding framework for bioprospecting activities. Although these legislative efforts are formulated in accordance with the particular situation of each country, they may also serve to illustrate public policy approaches which can be of use to other countries in the region.

2.1 Biodiversity Law, Costa Rica

The Biodiversity Law of Costa Rica was approved on April 23, 1998. Over the course of twenty years Costa Rica had put legislation into place which regulated natural resources including: the Constitutive Law for the National Parks Service (1972) the Law for Wildlife Conservation (1992) the Organic Law on the Environment (1995) and the Forest Law (1996). However, until enactment of the l998 legislation legal openings still existed within the legislation to more thoroughly cover the regulation of genetic resources and access to benefits. Costa Rica was a leader in setting up Cooperative Research agreements (CRA) with organizations, companies or others seeking to benefit from the country's rich biodiversity resources. Prior to the approval of its national Biodiversity Law there had been six contracts signed with transnational companies seeking to engage in biodiversity prospecting. The experience from negotiating these CRA's provided valuable experience in the development of the final legislation.

Costa Rica's Biodiversity Law is based on the guidelines of the CBD and is in full compliance. One component of the law affects the collection of whole organism samples for research purposes. Another component regulates taking of the next step involving extrapolating genes and active compounds, even if for research purposes only.

2.2 CGEN, Brazil

The *Conselho de Gestão do Patrimônio Genético* (CGEN) is the agency with the responsibility for coordinating and implementing the policies for the management for the genetic patrimony of Brazil. Established under a new federal government April 2003, the agency is also in charge of establishing the specific regulations for this management purpose. Pursuant to the provisions of the Convention on Biological Diversity, Brazil has made a continuous effort to adapt its public policies directed toward the conservation of its biological resources. The CGEN is intended to provide the legal and political instrument for purposes of regulating access to the genetic resources of the country while maintaining the necessary safeguards to protect the natural resources as well as the rights associated with traditional knowledge of the same. A number of presidential decrees have also served to provide guidelines for purposes of access to said resources. These dispositions have enabled a certain amount of commercial bioprospecting activity to be carried out until permanent provisions are in place.

One of the challenges of these regulatory efforts has been the need to avoid making the regulations so cumbersome that they would discourage the potential scientific and commercial research it was intended to facilitate. It is clear that the legislation was intended to be sufficiently strict to protect the interests of indigenous groups and of the country as a whole against unauthorized outside exploitation or so called "biopiracy". With the purpose of simplifying the procedure to obtain authorization for research, the Ministry of the Environment is also involving the Instituto Brasileiro do Meio Ambiente (IBAMA) to handle requests which do not involve bioprospecting or technology development and do not require access to indigenous knowledge. CGEN will continue to be the authorizing agency for access to genetic resources with potential economic use as well as scientific research involving indigenous knowledge.

2.3 Bioprospecting legislation, Chile

There are procedures in place in Chile which provide the basis for access to plant genetic resources in the country. The procedures apply to interested national parties as well as for those from other countries. Since 1995, the Ministry of Agriculture has placed such authorization capacity in the Institute for Agricultural Research (INIA) through the framework of the National Program for Protection and Conservation of Plant Genetic Resources. This disposition has allowed INIA to

establish contracts for access to such resources and also to monitor an equitable distribution of benefits that would derive from their use in accordance with the provisions of the CBD.

There is also newly proposed legislation that is being considered to expand and elaborate the provisions of laws to regulate access to genetic resources. The legislation under consideration specifically seeks to provide clear and concise guidelines for making genetic resources available to interested parties on an equitable basis, providing incentives for all concerned. The legislation under consideration specifies the appropriate government agencies whose functions dictate their involvement as well as the procedures to be put into place which would allow for soliciting authorization. Special emphasis is put on this legislative effort to maintain the process as simple as possible with maximum transparency and consideration for the protection of Chile's genetic resources and their potential use for economic and social benefit (Aguero, 2005).

Although this proposed legislation deals primarily with access to genetic resources, it is also of interest to the Chilean firms that produce phyto-pharmaceuticals from the natural resources in the country. According to Marcela Samarotto, area specialist at the *Fundación para la Innovación Agraria* there continues to be a constant search for new compounds which may be of medicinal value. There is significant interest in providing the scientific background and context with which to make claims based on popular knowledge of known natural sources. She reports that there are several Chilean companies that process and market phyto-pharmaceuticals. Additionally, she cites the existence of indigenous-based efforts among the Mapuche to commercial some of their commercial-based plant medicines. Intellectual property is not an issue with these products.

One of the small Chilean phyto-pharmaceutical companies is headed by Ximena Polanco whose company carries her name. One of the issues faced by the company is to place Chile's plant-based compounds on international markets. Such products need to conform to pharmacopeia standards. Her firm is helping to developing background monographs to document any claims that such products may make. Her firm produces the extracts and collaborates with the University of Chile to provide the scientific analysis on the target compounds. Her firm is also in the process of working to get Good Manufacturing Practices (GMP) certification and will need to provide adequate physical facilities, equipment, quality control and quality assurance protocols. The company is looking for partners in order to access outside markets. Many of their source plants are now domesticated and are being produced under conventional agricultural conditions. In the area of technological challenges, the company is eventually looking to the use of DNA technology to accurately identify individual plant species from which their product extracts are derived.

Regarding the laws which regulate the use of medicinal plants and herbal remedies, Ximena Polanco states that there are sometimes problems and inconsistencies in the approval of products. One example is that a major US producer General Nutrition Company (GNC) may sell products like Ginko Biloba in Chile as a nutritional supplement, whereas the Chilean laboratories must have the same item approved as a medicinal product by the Ministry of Health. There are other product inconsistencies of this type. Regarding indigenous knowledge in Chile, groups like the Mapuche are covered by a law for indigenous people that allow them to sell all kinds of traditional health products without necessarily having to provide toxicology information or other compound analysis on the products sold.

3. Selected experiences

In order to better understand some of the policy issues discussed in the foregoing section, it may be helpful to examine bioprospecting experiences at the institutional level. The following sections describe three fairly well-know efforts, highlighting key accomplishments as well as some of the resulting difficulties.

3.1 InBio, Costa Rica

General description: Costa Rica's *Instituto Nacional de Biodiversidad* (INBio), the National Institute of Biodiversity was created by an act of the national legislature in 1989, as a non-profit, public-interest, private institution dedicated to the conservation of biodiversity through research. Its mission is, "To promote awareness of the new biodiversity and thereby achieve its conservation and use to improve the quality of life". INBio operates on the principle that a tropical country must conserve major portions of its biodiversity by subscribing to a philosophy that biodiversity can be used in sustainable ways for commercial output that also promotes economic development. As noted on the INBio website, what began as a national program has now become part of an international initiative with the purpose of integrating conservation and development which will impact the pharmaceutical, medical, biotechnology, cosmetics, food and agricultural industries.

Costa Rica is relatively small in relation to the rest of Latin American but its approximately 51,100 km is home to an estimated 500,000 species of plants, animals and microorganisms representing about 5% of all the world's diversity. The country has dedicated approximately one-third of its territory to conservation of its rich biological diversity. They ascribe to a National Biodiversity Conservation and Sustainable Use Strategy based on the principles of "save, know, use". According to Rodrigo Gámez, CEO of INBio, "Save" means protecting representative samples of the country's biodiversity through a system of protected areas. "Know" means knowing the biodiversity that exists in the country and particularly in its protected areas, and "Use", means using sustain ably this biodiversity for the social and economic benefit of the country" (Gámez, 2003).

InBio has gone from prospecting for chemical substances and extracts from plants to prospecting with biotechnology-based tools that have enabled it to target secondary metabolites and genes. InBio's main source of materials has been through contributing groups and organizations. However, as the institute has become more client oriented with companies, it has needed to be able to manage confidentiality issues and to build an institutional capacity for contract research. Regarding indigenous knowledge, InBio does not depend on indigenous groups for leads on plants and compounds. They primarily source from the national protected areas which are uninhabited.

Agreements: INBio embarked on a pioneering arrangement, the first of its kind with Merck and Co. for the purpose of searching for novel compounds that could be of benefit to the pharmaceutical industry. In 1991 INBio signed the first Research Collaboration Agreement (RCA) with Merck and Co. The legal framework and conservation agenda have been much discussed in the literature of international biodiversity and still serve as a model for similar arrangements between countries rich in biodiversity and companies that seek access to potential as yet undiscovered compounds.

Under the RCA between InBio and Merck, the company was given limited access to samples from natural resources for a specified time period. The criteria was established by national legislation and supported by legal arrangement between InBio and MINAE, the Ministry of the Environment and Energy (MINAE).The bulk of the scientific research was to take place in Costa Rica and the research costs were to be assumed by the company. As appropriate, MINAE would receive a small portion of the research budget for conservation purposes. Benefit sharing mechanisms were negotiated beforehand including: milestone payments for discovery and development, a percentage of royalties on net sales of a final product, and application of intellectual property rights.

As a result of this collaboration, Merck received many samples of new, diverse resources to research as candidates for novel compounds. The company was assured that there would be a significant supply of compounds to offset the costs of a screening program. Merck agreed to limited

sharing of intellectual property rights and agreed to pay for these resources at determined market prices. For INBio, under terms of the RCA, local capacity building was assured. Many Costa Rican scientists were trained in state-of-the-art technologies. INBio was able to develop a formidable infrastructure and laboratory capacity to do work in bioprospecting which included high-throughput screening, isolation and characterization of compounds, and testing for bioactive properties.

InBio's agreement with the company Diversa over a ten-year period resulted in the development of two products: Cottonase and Green F-P (green florescent protein). The terms of the agreement provides for INBio to receive a percentage of the royalties derived from the sale of the products. One half of this income will be allocated directly to the Fund for biodiversity preservation (Nacion.com. 2005).

Local Costa Rican companies may not be really ready to manage bioprospecting activities under the new rules. The intellectual property issues are a little too complex for them. InBio on the other hand has developed the know how to manage intellectual property and it is also comfortable with basic research activities. Because of the relative lack of investment capital in Costa Rica, InBio has been active in trying to convince international banks to create a kind of an investment fund.

Other INBio agreements: After the initial RCA with Merck, INBio used this approach in subsequent negotiations as listed below including those with major technology groups and pharmaceutical corporations. The following chart indicates significant research collaborative agreements with industry and academia.

TABLE 4
INBIO PARTNERSHIPS

Industry or Academic partner	Natural resources accessed or main goal	Application fields	Research activities in Costa Rica
Cornell University	INBio's capacity building	Chemistry	1990-1992
Merck & Co	Plants, insects, micro organisms	Human and animal health	1991-1999
British Technology Group	DMDP, compound with nematocidal activity	Pest control	1992-present
ECOS	*Lonchocarpus felipei*, source of DMDP	Pest control	1993-present
Cornell University and NIH	Insects	Human health	1993-1999
Bristol Myers & Squibb	Insects	Human health	1994-1998
Givaudan Roure	Plants	Fragrances and essences	1995-1998
University of Massachusetts	Plants and insects	Biological pest control	1995-1998
Diversa	DNA from Bacteria	Biotech industry	1995-present
INDENA SPA	Plants	Human health	1996-present
Phytera Inc.	Plants	Human health	1998-2000
Strathclyde University	Plants	Human health	1997-2000
Eli Lilly	Plants	Human health and agriculture	1999-2000
Akkadix Corporation	Bacteria	Pest control	1999-2001
Follajes Ticos	Plants	Ornamental horticulture	2000-present
La Gavilana S.A.	Trichoderma spp	Biological pest control	2000-present
Laboratorios Lisan S.A.	None	Phytopharmaceuticals	2000-present

(continues)

TABLE 4 (Conclusion)

Industry or Academic partner	Natural resources accessed or main goal	Application fields	Research activities in Costa Rica
Bouganvillea S.A.	None	Biological pest contro	2000-present
Agrobiot S.A.	Plants	Ornamental horticulture	2000-present
Guelph University	Plants	Agriculture and conservation	2000-present
Florida Ice & Farm	None	Technical and scientific support	2001-present
Chagas Space Program	Plants, fungi	Human health	2001-present
SACRO	Plants	Ornamental horticulture	2002-

Source: Gámez, 2003.

In recent years, INBio entered into an agreement with the University of Costa Rica (UCR) whose Nuclear Magnetic Resonance Spectroscopy Unit (UE-RMN) located within the School of Chemistry enables analysis of selected organic and some inorganic compounds. Current bioprospecting activities include but are not limited to: training in bioprospecting collection techniques, identification and search for species for commercial interest; photochemical validation of medicinal plants and development of phytopharmaceutical extracts; analysis, isolation and characterization of organic compounds. INBio has a cataloged collection of more than 3 million specimens (INBbio, 2005).

3.2 Bioamazônia, Brazil

The Brazilian Association for the Sustainable Use of the Biodiversity of Amazônia (Bioamazônia) was created by a presidential directive in 1999 as a semi-governmental "social organization". The organization was charged with managing the genetic resources of the multi-state region known as "Amazonia" and was permitted to enter into business relations with companies. The organization was also given responsibility to coordinate PROBEM/Amazônia, the Brazilian Program of Molecular Ecology for the Sustainable Use of the Biodiversity of Amazonia. This is a working group formed for the purpose of implementing a program for the sustainable use of Amazonian biodiversity.

In 2000, Bioamazônia signed an agreement with Swiss Pharmaceutical giant Novartis Pharma AG which allowed the latter exclusive access to Amazonia's biodiversity. It allowed Novartis to have access to up to 10,000 samples from the Amazonia biota. It also gave the company rights over the commercial products developed from Amazonian plants and microorganisms. Over a three year period, Novartis agreed to pay Bioamazônia some US$ 4 million, as well as one percent of royalties from any drugs developed.

The deal brokered over the contract created a huge societal debate. The contract was entered into without consultation from Bioamazônia's scientific advisory council and members of the Brazilian scientific community were upset. Subsequently the arrangement was challenged by the Brazilian Ministry of the Environment and the agreement was suspended. Following this, the Brazilian government created an inter-ministerial commission charged with controlling bioprospecting in Brazil.

3.3 Chiapas, Mexico

The state of Chiapas in Southern Mexico, home to Mayan people for thousands of years, is also among the most biologically diverse areas of the world. For four decades, Dr. Brent Berlin an ethno biologist and anthropologist from the University of Georgia (UGA) has studied Mayan medicinal

plants in Chiapas. Dr. Berlin is fluent in Tzeltal, one of the Mayan languages spoken in the highland community. Approximately eight years ago, he began a project to promote the use of local herbal medicine while undertaking a comprehensive survey of plant species used by Mayans in the region. The project was also designed to preserve traditional knowledge while possibly generating monies for the local population.

The project was funded in 1997 by a grant of $2.5 million dollars from the International Cooperative Biodiversity Group (ICBG) The ICBG program was initiated in 1991 to address the interdependent issues of drug discovery, biodiversity conservation, and sustainable economic growth and was sponsored by the National Institutes of Health (NIH), the National Science Foundation (NSF) and USAID. The organization's stated purpose was "to guide natural products drug discovery in such a way that local communities and other source country organizations can derive direct benefits from their diverse biological resources" (ICBG, 2005).

Dr. Berlin's project involved working with a local university, El Colegio de Frontera Sur (ECOSUR) in San Cristobal del as Casas, Chiapas. As part of the agreement, the University of Georgia had developed an arrangement for distributing profits from the research among the parties involved. This included setting up a trust for local Mayan people. Included in the distribution were: The University of Georgia, ECOSUR, and Molecular Nature, a company based in Wales which provided a plant biology laboratory at ECOSUR to train local researchers.

From the beginning, the local research group had encountered limited success in communicating its approach, since the Mayan language does not contain words for either 'gene' or 'patent'. In order to better explain their proposed procedures, the project staff decided to take advantage of a common Mayan cultural practice of putting on dramatic presentations. In more than fifty such presentations, the UGA team and ECOSUR trained local Mayans to act out skits about collecting and labeling various traditional plants. The Mayan 'actors' even put on white lab coats to show how the plants would then be tested.

In spite of what appeared to be some success in using the medium of theater to communicate the project's purpose, several local action groups, the OMIECH and the Council of Traditional Healers, countered that these presentations were in fact a vehicle to mask the ICBG's "true purpose" of commercial exploitation.

In early 1999, the ICBG-funded project came under fire from outside forces, principally an organization in Winnipeg, Canada the Rural Advancement Foundation International (RAFI) which has since changed its name to Erosion, Technology and Concentration (ETC). RAFI attacked the project by firing off a volley of articles with provocative titles such as "Biopiracy in Chiapas". These commentaries raced around the Internet alleging that local people had not been properly informed about the nature of the project. Further complications ensued in July 2000 when there was a major change in the federal Mexican government under newly elected President Vicente Fox. A halt was placed on issuing further collection permits and the government declared the need to overhaul Mexico's bioprospecting legislation.

The challenges to this project and lessons to be learned relate in part to the complexities of Mexican law combined with strong worldwide anti-globalization sentiments which seeped into local politics and the colored the research agenda. According to Dr. Berlin, "On the question of "whose property" (the natural resources themselves) Mexican law is clear: Mexico owns its natural resources. Permission to *collect* these resources, however, lies with the legitimate owners of the land on which the natural resources are found. No governmental or non-governmental agency, such as OMIECH and the Council of Traditional Healers, can grant this permission. Furthermore, the rightful owners of the property on which the natural resources have been collected are those who

have claim to equitable compensation for financial benefits that might accrue from the biotechnological use of these resources" (Berlin, 1999).

The OMIECH, supported by the RAFI, leveled the charge that the ICBG was studying ethno medical knowledge. However, according to Dr. Berlin, his research was not directed at specialized knowledge but rather at the generalized knowledge of medicinal herbs widespread among the Highland Mayans. In fact, the ICBG project attempted to address the issue of intellectual property by establishing a non-profit association, Promotion of the Intellectual Property Rights of the Highland Maya of Chiapas, Mexico (PROMAYA) to equitably distribute any funds resulting from the proposed project. Complications revolving the concept of collective ownership of traditional knowledge are a challenge to existing patent law. According to Dr. Berlin, the demands of OMIECH and the Council of Traditional Healers to be granted control of all natural products research efforts in the region and to determine any distribution of funds resulting from such research did not represent the 'best interests' of the other Mayan communities that had already agreed to collaborate on the ICBG project. In the end ECOSUR withdrew its collaboration because of the political climate and the project came to an end.

These factors contributed to undermining the ICBG project. According to Joshua Rosenthal of the NIH, although pressed fumigated botanical specimens were collected during the first year of the project for taxonomic purposes, the ICBG never initiated collections for drug discovery. First year collections had been allowed under a permit issued by the Mexican government and when that permit expired collecting was suspended. As Rosenthal commented on the dissolution of the project, "The controversy that has led to the termination of the Chiapas ICBG may have a chilling effect on the ability of scientists to develop transparent and ethical collaboration in natural-products drug discovery, biotechnology and other sustainable uses of biodiversity for local and global benefit. In our opinion all parties have lost, not least local communities in developing countries" (Dalton, 2002).

III. Examples of bioprospecting companies in selected LAC companies

The following sections describe the criteria for selection of firms engaged in bioprospecting activities as well as the variables of interest.

1. Criteria for selection of companies

Given the relatively small number of firms currently involved in bioprospecting activities in the LAC region, the criteria for the selection of firms to be profiled in the study is necessarily inclusive. In this regard, it is necessary to consider all bioprospecting-related activities as links in the productive value chain associated with new and traditional industries in the region. It is also of interest to examine the experiences of firms that have failed, closed or otherwise gone out of business.

The present study reflects certain underlying assumptions about the factors which affect and define the outlook for commercial bioprospecting activities. The following assumptions were included in the original proposal for this study:

1. The technological and market environments in which bioprospecting activities operate are subject to increasingly rapid changes which require continuous strategic adjustments on the part of the bioprospecting firms in the LAC region.

2. The capital requirements and the extensive timeframe for product development in the life science sectors serve to restrict new entries in the area of commercial bioprospecting.
3. Local start-up bioprospecting business initiatives in the LAC region benefit from international partnerships with entities outside the region, although there is a variation in the types of partnership models and related terms of collaboration.
4. Commercial bioprospecting experiences in other regions of the world have relevant lessons and potential alliances for Latin America and the Caribbean.
5. Often inconsistent and unclear public policy positions put forth by national governments and regional agreements regulating access to local genetic resources are affecting the ability of bioprospecting-based firms to thrive.

While it is not intended that the proposed study necessarily prove or disprove any of the above-mentioned statements, these assumptions and others served to guide the gathering of information leading to the formation of an updated picture of the commercial bioprospecting activities in the region. While the focus of this report is on individual locally owned firms in the LAC region, relevant aspects of international firms operating in the area are also of interested and are referenced accordingly.

Firms and institutions included in this study share some or all of the following characteristics:

- For profit or non-profit status,
- Engaged in bioprospecting activities in the LAC region,
- Current or recent operations,
- Publicly or privately held,
- Focus on whole organism, micro-organism, genetic level,
- Medical, agriculture or industrial applications,
- Product or service orientation,
- Representative of the other bioprospecting firms in the region.

2. Variables of interest

The profiles for the firms and institution covered in this study contain both demographic and performance variables.

The demographic variables generally include:

- type and location of enterprise or institution,
- product focus,
- establishment and evolution of the firm or institution;
- financing sources,
- numbers of employees,
- proprietary technology and technology platform,

- geographic area of operation,
- existing political, institutional, educational, economic, environmental, and legal context.

Where possible, and when available, information on **performance variables** may include:

- financing mechanisms for the firm's activities,
- revenues and profits (if any),
- corporate and institutional relationships,
- use of outside services,
- market niches in which the firm operates,
- formation and evolution of the firm,
- role of government in the establishment and subsequent performance of the firm,
- barriers and problems faced by the firms in the regulatory area, financial,
- markets, intellectual property,
- agreements and partnerships for national and international cooperation with,
- other firms, universities or research institutions,
- short-term and long-term actions that government and the financial, educational,
- research and business communities can take as individual countries and in regional coordination,
- patenting activity.

Again, where available, information is provided on the nature and structure of any arrangements entered into with indigenous groups and/or governmental bodies.

3. Company profiles

The individual descriptions are presented below for the firms which were selected in accordance with the previously listed criteria. These are: Extracta Moleculas Naturais (Brazil); Natura (Brazil); Lisanatura (Costa Rica); Fundación Biociencias (Chile); Bioscan (Chile); Kina Biotech (Peru). Each of these firms is discussed in terms of their principal mission and any bioprospecting-related activities they have pursued. As the firms included here differ considerably in terms of their respective sizes, the nature of their products and services, and the extent of their bioprospecting-related activities, not all firms will be profiled at the same level of detail.

3.1 Extracta Moleculas Naturais, Brazil

General description: The bioprospecting company Extracta Moleculas Naturais was created in 1998 with offices and laboratories in Rio de Janeiro, Brazil. This company conducts research on Brazil's plant resources to identify, isolate and characterize natural molecules of value to pharmaceutical companies and related industries. The company was the first to receive a two-year authorization to explore the genetic resources of plants in the Amazon region and in the Atlantic coast.

During the relatively short period of time since its founding, Extracta has developed the largest library of natural chemical compounds in Latin America. Its initial growth and development was

supported by highly-skilled managerial leadership, world-class research capabilities and early success in obtaining contracts with major international pharmaceutical companies.

Unique type of firm: Although other firms in Brazil have pursued phyto-pharmaceuticals and drug-based therapies using whole plant extracts, there are no other firms in the country with business models similar to Extracta's. The company's specialized technology enables it to target precise molecules and pure compounds. It is also distinguished by its level of organization in collection procedures, technological platform, licensing policies and other business aspects.

In addition to being a pioneer in its field, Extracta is also the first Brazilian company to be licensed by the agency which is charged with regulating bioprospecting in that country, the **Conselho de Gestão do Patrimônio Genético** (CGEN) which is described in a separate section of this report. One of the main benefits to the company of receiving this license was that it enabled it to access public financing. It also allowed Extracta to resume its negotiations with international clientele.

Client-Oriented Staff Flexibility: The Company has maintained an effective business strategy which has allowed it to adjust its professional staff and operational scope in accordance with client-based workflow. Extracta enjoyed a major expansion after securing a key contract with the pharmaceutical company Glaxo Smith Kline in 1999. After the Glaxo contract was completed, the company was reduced by about 60 scientists twenty of whom were at the Ph.D level. Extracta currently maintains a small group of less than a dozen staff persons, including researchers and associated support staff. However, the company retains its working relationships with its large pool of previous researchers who are prepared to return to project assignments as the need arises. As Extracta's initial formation was completed within the BioRio efforts of the Federal University of Rio de Janeiro, the company maintains active ties with that institution, particularly with regard to the involvement of scientists and researchers. Extracta has also done work with another large biotechnology company, the Massachusetts, USA based Genzyme Corporation. Even though this company already has a large chemical data bank of its own it has demonstrated increased interest in natural compounds found in Brazil for purposes of its research on genetic diseases. Extracta is in a good position to partner with such firms.

Financing: The total investment in Extracta to date is approximately US$ 5 million. The company's original financing provided for shared ownership among the founder, local commercial banks and a foundation. The founder has now re-acquired outstanding shares and owns up to 87.5% of the company. The company is not currently planning to sell shares on the public stock market until it can accumulate more years of demonstrated financial performance. Although Extracta is eligible for discounted loan capital from special agencies of Brazil's federal government, the company currently does use any of these federal sources. According to Extracta's CEO, Dr. Antonio Paes de Carvalho, "Extracta today has zero public resources" (Paes de Carvalho, 2005).

A recent article on Extracta notes that it may have some additional avenues opening up from venture capital sources. The Brazilian Association of Venture Capital (ABCR) is in active discussions with the Brazilian Association of Biotechnology Companies which is also presided over by Dr. Carvalho. The head of ABCR has affirmed his organization's intention to foment and encourage the various fledgling entrepreneurial efforts in the country (Guimarães).

Market issues: Partially due to the highly specialized nature of Extracta's work and partially due to the fact that its typical market profile consists of large pharmaceutical firms, the company's management is currently challenged with having to re-establish its client base. This is an important priority for the company as it looks to the U.S., Europe and Asia for this purpose. The large European pharmaceutical companies are especially significant targets, although some of these firms

channel their Latin American business through subsidiaries in Spain and Portugal. Extracta management feels that this constitutes a disadvantage.

Returns on investment can still be a long-term proposition. According to Dr. Paes de Carvalho, Extracta's first molecules will probably not reach the market for "approximately 8 to 10 years after being identified". Although the high-risk biotechnology market cannot always guarantee returns, any portion of the world market on any of the pharmaceutical industry's blockbuster drugs can provide a significant incentive for firms like Extracta.

Role of government: From the beginning of its operation, Extract's reliance on government has remained limited. Even its own founding benefited more from a university sponsored support effort linked with the Rio de Janeiro-based technology park known as Bio Rio. Bio Rio is an example of a university and private sector effort that has done very well over the last 20 years relatively independent from the ongoing changes in the government. The University is at the heart of this effort. Extracta represents a point of interface between science and industry. Small technological enterprises like Extracta in many ways allow university research results to be part of the industrial innovation picture.

While the company does not directly rely on government for its financial viability, Extracta is active in the Brazilian Association of Biotechnology Companies (ABRABI) and has exercised some leadership in that association's approach to governmental policies and regulations, taxation provisions and related issues. Extracta and other technology-based firms will benefit from a new governmental disposition issued in June 2005 dealing with various issues of interest to the private sector. Titled "*Medida Provisoria #252*", this disposition, although temporary, has the full effect of law. This legal disposition has provided companies like Extracta with the means to address taxation rates associated with the importation of certain technologies required for its high-throughput screening services.

Another such temporary disposition is under consideration which deals specifically with issues of access to genetic resources. The new "*medida provisoria*", expected to be issued sometime in October of 2005, was advocated for by ABRABI and by the Centro Empresarial Brasileiro de Desenvolvimento Sustentavel, based in Rio de Janeiro.

Extracta's bioprospecting practices: Extracta's policies and practices for gathering and classifying natural materials provide for dealing directly with individual property owners who receive 2.5% of any royalties eventually generated by the resulting product. The property owners are expected to follow strict protocols for collection and custody of the materials. Extracta has focused almost exclusively on Brazilian biodiversity resources but does not make use of indigenous or traditional knowledge in its collection activities. Dr. Paes de Carvalho reported in a recent interview that Brazil's natural resources contain 65,000 species of plants of which 1,400 are known to have elements of medically significant activity (Guimarães, 2004).

As part of its strategy for the extraction of new compounds, the company has signed an agreement with the Federal University of Pará in Belem, where Extracta has helped to equip a laboratory at that institution for purposes of processing samples. In addition to the laboratory benefit for the University, interesting opportunities are generated for the participating faculty and students.

TABLE 5
EXAMPLE OF HYPOTHETICAL BENEFIT SHARING WITHIN AN EXTRACTA PROJECT

Part 1: Providers (up to 15% of all projects that utilize their material)
- Authorization to collect (2.5%)
- *Execution of Collection (1%)
- Provision of reliable taxonomic classification (2.5%)
- *Crude extract production (9%)
Part 2: Scientific/Technological Partners (up to 35% in a project)
- Analytical Chemistry (17.5%): from Plant Chemistry to Planar Structure
- Biological Activity (17.5%): from Target and Bioassay Development to Mechanism of Action and "in vitro" ADMeTox
Part 3: Extracta (50%)
- Semi-Automated High Throughput Screening (HTS) and Bioassay-directed Pure Compound Quantity Isolation (HPLC, LC-MS) (25%)
- Business and Technology Prospecting, Contract Execution Management (10%)
- EXTRACTA Chemical Biodiversity Bank Curatorship (5%)
- Development and Maintenance of the Bank Database (5%)
- Intellectual Property Representation and Administration (5%)

Source: Extracta * guidance and training by Extracta.

3.2 Natura Cosmeticos S.A., Brazil

General Description: Natura Cosmeticos SA, Brazil's largest cosmetics company is multi-million dollar business based in São Paulo, Brazil that includes a product (the Ekos line) that was developed as part of a strategy for sustainable use of Brazilian biodiversity and uses among other things extracts from the Brazilian shrub, guarana. The Ekos line also includes sustainable products from the rainforest such as Andiroba, Brazil Nut, Buriti, Chamomille, Cocoa, Cupuaçu, Pitanga. Passion Fruit, Brazil Nut, Macela do Campo, and Mate Verde. These ingredients are found in cultivated and extractive reserve areas which have been registered with the Brazilian Environment and Natural Resources Institute (IBAMA). Founder and CEO Luis Seabra runs a company which counts on more than 2700 employees and has expanded beyond Brazil to Chile, Argentina, Peru, Mexico and in spring, 2005 opened up a store in the exclusive Saint Germaine de Pres neighborhood in Paris, France.

Markets Served In 2002, Natura made $1.9 billion (Reais) in five South American countries: Brazil, Bolivia, Chile, Argentina and Peru. In 2004, the company sales showed a growth of 33% over the past three years. During the third quarter of 2005, the company registered a net profit of 100.9 mln Brazilian reais ($44.12 mln/36.38 mln euro) for the third quarter of 2005 which was a 30 percent year-on-year growth. Net revenue stood at 571.4 mln reais ($249.87 mln/206 mln euro) for July to September 2005, a 27.5 pct year-on-year increase (D'Ambrosio, 2005).

Natura sells its products primarily through sales representatives who market directly to customers. In 2004 the company contracted with 454,000 direct sales representatives in Brazil and another 26,000 abroad. The number of associates is up 21% from the previous year. Their product line includes more than 600 products: make-up, fragrances, bathing, hair, facial and body treatment, sun protection and oral hygiene. The company has invested more than $47.4 million (Brazilian reais) in research and development. One of their technological innovations was the introduction of an internationally patented product – Elastinol+R used in their Chronos line. In 2004, 177 million units were sold in Brazil and abroad (Natura Annual Report, 2004).

As noted in all their published literature, Natura Cosmeticos has made a commitment to a development model that promotes social justice and environmental preservation. They have taken specific steps to develop relationships with communities that supply the company with raw materials from Brazilian biodiversity including active participation with local governments. The company made an assessment in 2004 to look at the environmental impact of its packaging and opted to increase the sustainable use of raw materials from Brazilian biodiversity used in packaging. Additionally they addressed other important environmental issues such as reuse of water used in production and reduction of waste from processing.

In 2004, they were one of the first Brazilian companies to sign a Global Compact that made a commitment to the principles proposed by the United Nations. Standing firmly behind a philosophy which supports social justice, equal rights for women, fair wages and is against exploitation of child labor, Natura's vision simply stated is: "The Company, a living organism, is a dynamic set of relationships. Its value and longevity are connected to its ability to contribute to the evolution of society and its sustainable development."

Activities in Bioprospecting When the company launched its 'Ekos' line in 2000 it made a commitment to the sustainable use of raw materials from Brazilian biodiversity. Since that time it has created a development model based on its experiences with the community of Iratapuru, in the State of Amapá .It is currently working with some 30 families that supply Brazil nuts, copaiba and breu branco. They are also supporting efforts of Amigos da Terra, an NGO that created a business management plan for certification of three raw materials produced by the community.

The company began a Project for Forestry Restoration in 2004. According to Sonia Tuccori, Head of research and development with biodiversity for Natura, "The company aims to be "socially just" with its supplier communities, recognizing the value of traditional knowledge of local flora and paying fair prices for the raw materials used in the cosmetics". Among the natural 'fruits of the forest' that are currently being used in Natura's product lines are: Andirobas, buritis (Mauritia vinifera), Brazil nuts (Betholletia excelsa), copaibas (genus Copaifera) and pripriocas (Cyperus articulatus, Kyllinga). This past year, the company added a new cologne to their perfume line using the extract of 'victoria regia" a giant aquatic flower from the Amazon whose blossom of 30cm in diameter is the largest flower to grow in the Americas (Osava, 2004).

Natura affixes a quality seal to all its products. Two organizations, the Forest Stewardship Council (FSC) and the Instituto de Manejo e Certificação Florestal e Agrícola (Institute for Forestry and Agricultural Management and Certification), Imaflora, are responsible for this certification. In 2004, the FSC seal certified six raw materials used by Natura: Brazil nut (Bertholletia excelsa), breu (Protium pallidum), copaiba (Copaifera spp.), rosewood (Aniba fragans), cacao (Theobroma cacao) and guaraná (Paullinia cupana).

TABLE 6
STATUS OF THE RAW MATERIALS

Status of the raw materials

Raw materials	State	PHASE I Beginning	PHASE I End	PHASE II Beginning	PHASE II End	PHASE III Beginning	PHASE III End	Notes
Andiroba *Carapa guianensis*	Amazonas	■	■	■				Traditional management
Buriti *Mauritia flexuosa*	Piauí	■	■	■	■			Traditional management
Cacao *Theobroma cacao*	Bahia	■	■	■	■	■	■	Agroforestry system
Lemongrass *Cymbopogon citratus*	São Paulo	■						Cultivation
Chamomile *Chamomilla recutita*	Paraná	■	■					Cultivation
Brazil nut *Bertholletia excelsa*	Amapá	■	■	■	■	■	■	Traditional management
Copaiba *Copaifera spp*	Amapá	■	■	■	■	■	■	Traditional management
Breu *Protium pallidum*	Amapá	■	■	■	■	■	■	Traditional management
Cumaru *Dipteryx odorata*	Em avaliação	■						Traditional management
Cupuacu *Theobroma grandiflorum*	Rondônia	■	■	■				Agroforestry system
Guarana *Paullinia cupana*	Bahia	■	■	■	■	■	■	Organic cultivation
Rosewood *Aniba ferrea*	Amazonas	■	■	■	■	■	■	Traditional management
Macela *Achyroclines satureoides*	Paraná	■						Traditional management
Passion fruit *Passiflora edulis*	Minas Gerais	■	■					Cultivation
Yerba Maté *Ilex paraguariensis*	Rio Grande do Sul	■	■	■	■	■	■	Traditional management
Murumuru palm *Astrocaryum murumuru*	Amazonas	■	■	■				Traditional management
Surinam cherry *Eugenia uniflora*	São Paulo	■	■	■	■	■	■	Organic cultivation
Flatsedge *Cyperus articulatus*	Pará	■	■					Cultivation

Target for 2005 Of the total 35 native or exotic species obtained in Brazil, which produce the natural raw materials used by Natura (essential oils, fixed oils and extracts), eight had their certification completed in 2004 (23% of the total). In 2005, the target is to include another five in the phase III of the certification process, reaching a total of 13 certifications (37% of the total).

Source: Natura Annual Report, 2004.

Another byproduct of this effort is an ecologically conscientious image that, especially in Europe is reflected in a growing market where the use of oils and extracts of native or indigenous origins becomes an advantage for the company on the international market where they might not otherwise be able to compete. As the green revolution continues to spread around the world, opinion polls reveal that consumers prefer products associated with a commitment to social and environmental responsibility. In November, 2005 in Rio de Janeiro Natura is taking part in Expo Sustentat, an International marketplace organized by Nuremberg Global Fairs in Germany which is held congruent with BioFach Latin America which focuses on the growing Latin American organic market.

3.3 Laboratorios Lisan S.A., Costa Rica

General description: Laboratorios Lisan is a pharmaceutical laboratory dedicated to research, development, production and commercialization of pharmaceutical and "phytopharmaceutical"

products for human and veterinary use. The company also develops and produces cosmetic-based health and beauty products. Lisanatura is a division within Laboratorios Lisan that is in charge of the line of natural pharmaceutical products based on plant resources in Costa Rica.

Lisanatura describes its approach to the development of phytopharmaceuticals as an "ethno-botanical" method based on the use of known plants. However, the firm does not rely on indigenous knowledge for this purpose. That is, the natural remedies that they research are derived from commonly recognized "folk" understandings in the public domain accessible to the general population. The firm will work with a given plant source recognized for its remedial qualities and produce a more purified formulation for which they provide standardized analysis and quality control information on the active ingredient involved.

One example is the use of the "quassia amara" plant known in popular vernacular as "*hombre grande*". A traditional use for this plant is to brew it as a "tea" often taken for digestive problems. What Lisanatura does is extract the active compounds from the plant and make them available in tablet form, with standardized measures of its purity and contents.

Intellectual Property Issues The company maintains a knowledge base of how the compounds function in the human body. The production processes used by Lisan are protected by patents and the company may seek additional Intellectual Property protection on new uses of some of its compounds. The topic of Intellectual Property protection is not yet very well developed in Costa Rica according to the Lisan representative interviewed. Now with the new discussions of the Central America Free Trade agreement with the U.S., there is more pressure to have an understanding of these issues. There is increasing interest in Costa Rica on Intellectual Property protection. The local industries feel the need to protect the local market from the flood of similar products arriving from China and other countries.

Market Considerations The size of the Costa Rican market is not necessarily sufficient to recuperate Lisan's research costs. The company is definitely looking at outside markets to compensate and recover its costs. They are particularly interested in the European markets. In Europe they refer to the type of products made by Lisan as "phyto-medicines" or "phyto-farmaceuticals" which have wide acceptance and increasingly sought after. Lisan considers the European consumer to be more conscious of the value of natural remedies and is appreciative of quality considerations. This enables appropriate pricing of the product. Accordingly, they ask for documentation regarding the source of the raw material used. From Lisan's standpoint, this could compromise the company with regard to disclosing its raw material sources and may invite the eventual elimination of their own value-added activities.

Regarding the U.S. market, there is less clarity on whether or not Lisan's product required FDA approval. The company has made inquiries into this matter but there are differing interpretations of the regulations even by U.S. firms involved with Neutraceuticals and similar products particularly with regard to the extent to which health claims can be made by the producers of these products.

Relationship with InBio Lisan entered into an arrangement with the Instituto de Biodiversidad (InBio) for the purpose of assisting the company with its capacity building and product innovation. This arrangement was helpful to the company to do phyto-chemical analysis. InBio was managing a program from the multilateral investment fund (MIF) affiliated with the Interamerican Development Bank. The arrangement with InBio required a return of the funds although without interest. Of the total valuation of the project, 20% would be put up by InBio, 30% from Lisan and 50% from the MIF fund. Of the 30% that would be required from Lisan, one half of that amount had to be in cash and the rest in in-kind assets in this program, InBio was looking for appropriate candidates for its MIF program. Lisanatura submitted a proposal for the development

of products involving six selected plants. This assistance was particularly useful given that in Costa Rica, there are no available funds to support R&D and no risk capital or venture capital. Lisan has not fully availed itself of private capital sources.

Lisanatura's project with InBio has already been completed and Lisanatura is in the process of pursuing product development. In 2004 there were five phytoparmaceutical products with a sixth to be launched later that year. Three plant extracts have been used to develop six phytopharmaceutical products including creams, gels and powders from *P. major*. *A. Vera* and a digestive pill made from *Q. amara* referred to earlier.

TABLE 7
DESCRIPTION OF EACH PRODUCT, ITS PRESENTATION AND THERAPEUTIC USES

Plant	Product	Presentation	Use
Aloe *(Aloe vera)*	Lisaloe ® Cream	15g tube	To alleviate skin redness and inflammation. Used to treat skin wounds and ulcers, burns, solar erythema (sunburn), sensitive skin and nipple fissures.
Amargo *(Quasi amara)*	Q-assia ® tablets	Blister pack of 10 tablets	Digestive aid in case of dyspepsia (uncomfortable sense of fullness after meals), to reduce stomach acidity and promote bile secretion
Plantain *(Plantago major)*	Encigel ® gel	15 g tube	Used topically as an anti-inflammatory and to treat mouth mucosal disorders (gingivitis irritations, minor wounds, canker sores)
	CS ® cream 1	15 g tube	Used topically as an astringent and anti-inflammatory, and to treat mild and moderate acne.
	Alivion ® cream 2	15 g tube	Used topically as an anti-inflammatory and antipruritus (against insect bites, itching, rashes).
	Soluble powder	3g packet	Digestive aid.
Fresh cut *(Justicia pectoralis)*	Estilo ® tablets	Blister pack of 10 tablets	Central nervous system sedative.

Source: Roadmap to Commercialization, 2004.

There will be a new opportunity in the coming months for Lisan to compete for non-reimbursable funds from a new competition which will involve universities in Costa Rica. The funds will derive from a new loan to Costa Rica from the Interamerican Development Bank .Lisan is in communication with the Ministry of Technology for this purpose.

Human Resources Recruitment and retention of qualified professionals to work as researchers in Lisan has not constituted a particular problem for the company. Lisan often receives inquiries from potential candidates in other parts of Latin America but their pay expectations are too high. Lisan has taken advantage of the available talent at Costa Rican universities. The academic positions in Costa Rica provide good benefits and are therefore highly sought after. Therefore, it is easier for Lisan to create contractual arrangements with some of the faculty or

researchers. They have a good working relationship with the *Instituto Tecnologico* which is a state university. The other two universities with which they work are the University of Costa Rica and the *Universidad Nacional*.

Benefits This project has produced positive benefits across the production line from the farmers who produced the raw materials to the technicians to the suppliers. There have been new jobs created as a result of demand for production and processing in the laboratory.

3.4 Fundación Biociencia, Chile

General description: The *Funcación Biociencia* was founded in 2001 and is based in Santiago, Chile. It is set up as a small private non-profit organization to offer research services in the area of analysis of bioactive compounds found in "extremophile" micro-organisms. These types of micro-organisms include those which are found to thrive in environments with extreme conditions such as high or low temperatures or high acidity or alkalinity, drought situations and others. Chile's geographic situation provides a wide variety of contrasting environments for this purpose.

The work of the *Fundación Biociencia* is focused on discovering any properties or characteristics which such organisms might have of potential interest for pharmaceutical and diagnostic purposes or other industrial applications. The organization states that it is also interested in developing molecular biology tools for decontamination, biomining, ecologically friendly detergents and other industrial processes.

Financing: The *Fundación Biociencia* was initiated with initial capital of about US $250,000 which was provided by the founders of the organization themselves. Although it currently generates about US$ 100,000 per year, the organization's operational strategy is counting on eventually being able to benefit from royalties derived from large industrial laboratory clients.

Although the services of the *Fundación Biociencia* are primarily provided through private research contracts, it also engages in self founded research, and research collaboration with other private institutions based on collaborative agreements with other private institutions and research funded by public or private grants.

Human resources: The *Fundación Biociencia* maintains a small staff of researchers which is expanded or reduced in accordance with the projects underway. It has trained its own people out of its research funds. It has also been able to occasionally attract qualified researchers from other countries for specific project activities. The cofounders, Olivier Rickmers and Dr. Jenny Blamey are both qualified professionals with an extensive network of resource persons from which to draw. Dr. Blamey is a specialist in extremophile organisms also directs the Genome Chile Program. Mr. Rickmers is trained in engineering and management. They recognize that they are pioneers in this area in Chile.

Government actions: With regard to government policies, *Fundación Biociencia*'s CEO, Olivier Rickmers, feels strongly that the Chile can benefit from establishing supportive infrastructure for general biotechnology development. He states that although there is often a propensity to devise public policies based on the experiences of other countries, the government will need to fully understand the various facets of assistance which constitute the needed support for entrepreneurially oriented firms. He is aware that there is legislation under consideration in Chile which addresses commercial bioprospecting activities. He agrees that there should be guidelines for bioprospecting activities, but that they should not be used to grant exclusivity of access to any particular regions. Similarly, Mr. Rickmers believes that Fundación Biociencia would be at a disadvantage if it had to compete with large companies for access to biodiversity areas.

Technological issues: *Fundación Biociencia*'s basic technological "know how" is in the area of isolation and management of live micro-organisms. The organization carries out basic and industrial research involving the sampling and isolation of special extremophilic microorganisms from severe ecosystems like hot springs, salt lakes, acid lakes, desert, lava fields, volcano craters, and places like Antarctica. The organization refers to this technology as the "comprehensive management of extremophiles". The *Fundación Biociencia* is also developing technology for extraction of active compounds. It has not done direct collections of thermophilic marine microorganisms. When necessary, it makes use of available culture collections.

Some of the technological methods in which the *Fundación Biociencia* has capacity are:

- Optimization of growth conditions and maintenance of cultures,
- Novel microbiological techniques to handle and work with extremophilic,
- Microorganisms under anaerobic and aerobic conditions,
- Microbial and Chemical Análisis,
- DNA analysis and phylogenetics,
- Study of kinetics and thermodynamic properties,
- Enzyme & Protein Purification and Characterization,
- Development of Purification Protocols,
- Harnessing of microorganisms for bioremediation and biofiltration of metal,
- Contaminated industrial liquids and waste,
- Others.

Markets: The target markets for the services of the *Fundación Biociencia* are outside of Chile. The organization has no local clients in Chile or even in other parts of Latin America. Mr. Rickmers states that there is no market in Chile for their services. His principal clients are the large foreign medical laboratories. Presently his organization has industrial research partnerships with some of the largest international pharmaceutical companies. He estimates that the current worldwide market for thermophilic organisms is upwards of US$250 million annually.

3.5 Bioscan, Chile

General description: Bioscan S.A. is a small biotechnology company based in Santiago, Chile. The primary activity of the firm is to offer services in the area of human and plant pathogen detection through the use of molecular diagnostics. The firm also provides reagents, equipment and kits to be used in clinical and investigation laboratories.

Established in 1994, Bioscan employs 16 persons in professional and administrative functions. The Chief Executive Officer of the company, Roberto Valladares, reports that Bioscan's scientific teams are focused on achieving appropriate biological-based solutions through the creation of new products and services. Bioscan is working with hospitals and clinics in Chile to develop a patient-based research program for the purpose of validating Polymerase Chain Reaction (PCR) as a diagnostic method. For most of its services, Bioscan's market is primarily in Chile but it also provides services and products to customers and clients in France, Morocco, Dominican Republic Uruguay, Brazil and Argentina. The firm is privately held.

With respect to bioprospecting-related activities, the company is working on the development of small molecules from seaweed for application in plant health and human health. As

part of this effort, Bioscan has patented a polysaccharide extracted from a red seaweed native to Chile that is used as a bio-pesticide with antiviral activity in plants. The company will continue to pursue bio-prospecting in the area of marine algae and development of small molecules from algae. The above-named patented application has been shown to have antiviral effects in tobacco plants. The company would like to apply up this line of research to other plant species and is continuing to conduct research on such new applications for this product. Bioscan is also developing projects related to the transformation of fruit trees, as well as "fingerprinting" of fruit species and the detection of animal pathogens. In March 2005, the company submitted a patent application to stimulate the immunity of plants after four years of research.

Technology applications: Bioscan's published information profile reports that the firm has developed polymerase chain reaction detection of 50 human pathogens related to gynecological and periodontal diseases. Utilizing this technology, the company has performed over 160,000 human pathogen detection assays, making Bioscan the leading supplier of this service in Chile. Currently, the company is participating in a clinical laboratory-based program of the College of American Pathologists (CAP). In the agricultural area, the company has also pursued commercial services using PCR for the detection of viruses in grapes, pip-fruits and stone-fruits. According to Bioscan, these tests are required for its clients to achieve certification from the Chilean agricultural sanitary authorities.

Market approach: As part of its market approach and clinical network, Bioscan works with approximately 800 medical professionals affiliated with the major universities, hospitals, and clinics in Chile. Outside of Chile, the company works to identify partnerships within specific countries in order to form joint-ventures, technology transfer activities and distribution services. In this latter regard, the company maintains an open partnering strategy. It has initiated some relationships with US-based institutions and companies in order to gain presence in the American market. The company has a sales force dedicated to servicing physicians, clinics and hospitals in Santiago as well as the region of Valparaiso and other large cities in the country. For its fruit tree services, Bioscan is marketing to the principal Chilean fruit tree nurseries. Because of their R&D in fruit and forest plant transgenics, they are looking to develop cooperative agreements with foreign institutions and currently have a cooperative agreement with a European university.

Interaction with Chilean government agencies: Bioscan is currently developing research relationships with Chile's National Institute of Agriculture Investigation (INIA) for "fingerprinting" of fruit trees. It has also participated in programs of the Chilean Economic Development Agency (CORFO) and the National Council on Science and Technology (CONICYT) (Valladares, 2005).

Bioprospecting regulations affecting Bioscan: Bioscan's CEO, Roberto Valladares, states that firms like his have been free to gather the red algae samples used in their business from public access areas on the Chile coastline. He recognizes that there is legislation in progress which will address access issues but feels that existing commercial practices must be kept in mind as the government considers the appropriate regulatory provisions.

3.6 Kina Biotech, Spain-Peru

General Description Although Kina Biotech is no longer in operation, it is included here as an example of a good business model for commercial bioprospecting discussing many of the issues and challenges. The idea for Kina Biotech S.L. was conceived in 2002 when founder, Dr. Carlos Malpica of Peru, met other Latin American executives studying for an International Executive MBA at a leading business school located in Madrid, Spain. Their vision was to begin a commercial venture which would take advantage of the biological diversity of Peru and Colombia. The new company received support from the Regional Council of Bizkaia (Diputación Foral de

Bizkaia) one of the Basque regional councils. The company was formally established in 2003 with backing from the Sustatu Bideberri Program as Kina Biotech SRL, with an affiliate in Peru.

According to Dr. Malpica, the name Kina was taken from the Quechua word for the "*quina*" tree, (*Cinchona officinalis)* whose active ingredient, quinine, is a prime example of natural product from the New World commonly used to treat malaria. Peru, along with the other Andean community of nations, Bolivia, Colombia, Ecuador and Venezuela are known to be a potential source for new and undiscovered pharmacological compounds.

Kina was set up to commercially develop natural resources from the Andean countries for use in the pharmaceutical, nutraceutical and cosmetic industries. Their aim was to make general framework agreements with each Andean country; subsequently the company engaged in specific agreements that would promote legal access to resources for Kina's clients while offering research tools and value-added services to help discover active ingredients. The company manifested a strong commitment to social responsibility recognizing that the Andean countries contained a wealth of biodiversity that needed to be developed within a context of environmentally safe practices.

The company's approach was to offer three types of licensing instruments:

1. A contract with a researcher, for access to resources in a certain region during a certain time.
2. A contract with a company whose researchers may have access to offer chemical libraries derived from compounds found in the extracts obtained by Kina Biotech. These can be used by companies to run therapeutic trials as a means to identify potential bioactive compounds.
3. A license for access to genetic resources. This includes access to the crude extracts of natural products which originate in the Andean countries. These resources were offered with information on the geographical and biological origin of the each compound. These are done for each country.

Permits: In accordance with company guidelines, and consistent with the terms of the Convention on Biological Diversity, Kina Biotech would set up a legal contract with an accepted authority in country with which it is working. In Peru, the corresponding authority is the *Instituto Nacional de Recursos Naturales,* which is part of the Ministry of Agriculture. The aim of this agency is to set up a research agreement with a given national scientific institution with which they intended to collaborate. Kina understood the need to obtain license agreements for knowledge generated by the scientific community in order to retain intellectual property rights. Contract arrangements were designed to observe the terms and guidelines of the decisions of the Cartagena agreement of the Andean Community of Nations.

Dr. Malpica cites the following decisions which affected his bioprospecting-related efforts in the Andean region.

- "Decision 345 of October 1993 defines the common provisions on the protection of the rights of breeders of new plant varieties;
- Decision 351 of December of 1993 establishes a common regime for copyright and related rights;
- Decision 391 of July 1996, sets out common provisions on access to genetic resources for commercial valorization purposes. This decision also makes reference to the intangible element –traditional knowledge– associated with the use of resources, although regulation of such knowledge is left to a future directive;

- Decision 486 of December 2000 defines common provisions on intellectual property. Patent rights come under this decision" (Malpica, Strategy® Today, 2004).

Challenges: Dr. Malpica notes that there has sometimes been difficulty in determining with whom to sign such agreements and Kina had experienced some frustrations relative to this task. For example, frequently government representatives with whom the company was dealing did not have an adequate level of understanding of the science and technology involved. Therefore the relationship with these individuals needed cultivation.

According to Dr. Malpica, negotiations in Peru were facilitated when all of the stakeholder representatives were able to sit down at the same time with one another. He states that it is important that all entities which form the collaboration benefit from their unique contribution: The sovereign state owns resources and regulates their use; the scientific community, which generates knowledge, holds intellectual property rights (patents), and contributes to technological development; the indigenous communities which hold the traditional knowledge and the intellectual property rights; and the companies that make investments, develop products, and attach value in the marketplace (Malpica, 2005).

Given the complexities of issues which frequently involve international contracts and intellectual property rights, some of the government agencies with whom Kina had to interact had their own legal departments. Those that did not have in-house counsel used the services of outside legal services. Dr. Malpica notes that "certificate of origins" will increasingly be required for all samples collected.

While Kina's original intention was to work with the entire group of Andean region countries, the company mostly operated with its contacts in Peru. Dr. Malpica commented that countries like Bolivia still require some preparation in their agency protocols in relation to the bioprospecting area. Kina has had limited cooperation with Colombia and Ecuador. The fact that Kina had more success in Peru is partly due to the fact that Peru has had more experience in handling bioprospecting requests. A major advantage has been that government agencies, indigenous group representatives, investors, and researchers are used to working together on these issues.

Although Kina's work with traditional groups was limited, the company had some success with the Aymara group which represents an ancient people with a pre-Columbian empire that spanned parts of the south-central Andes Mountains. The Aymara language is spoken by approximately 1 million people in the highlands of Peru and Bolivia. Kina had representatives participate in the research itself. It was important to ascertain who legally represented this indigenous community. In Peru certain indigenous groups would agree to collaborate but lawyers who became involved would sometimes complicate the matter. Peru lacks significant numbers of lawyers trained in the legal complications related to bioprospecting law and according to Dr. Malpica provisions of CAN's Decision 391 mentioned earlier in this report need to be properly understood and practically applied.

Ultimately, Kina Biotech's operation was not able to continue for lack of operational capital. Its survival required a stronger base of investment funds and the guarantee of a minimum of a certain number of contracts per year. Dr Malpica is currently in the process of closing down the company. Together with another Spanish firm, he is exploring applications of advanced software to be used in bioprospecting activities (Malpica, August 2005).

IV. Observations and policy considerations

This study has presented a general review of the activities involved in commercial bioprospecting in Latin America and has offered specific insights on the nature of the business dynamics at the company level. The firms and institutions discussed in this review were chosen to reflect a cross-section of the types of endeavors associated with commercial bioprospecting in selected countries of the region. Although the sample size was not necessarily intended to be representative of the total number of companies in the region engaged in said activities, the discussion serves to illustrate particular aspects relevant to the viability of the enterprises and their future contribution to the economy of the respective countries in which they operate. The issues of particular interest for purposes of addressing public policies at the national and regional level are summarized below.

Types of commercial bioprospecting activities: Although there is a wide array of types of commercial bioprospecting activities in LAC countries, this study has pointed out that there are relatively few firms operating in the region that are dedicated to bioprospecting as an exclusive activity. The heavy capital requirements and the extensive timeframe for product development in the life science sectors serve to restrict new entries in the area of commercial bioprospecting for purposes of finding new drug leads.

The types of firms discussed in this study include those that are dedicated to the direct collection, isolation and characterization of bioactive molecules and micro-organisms for industrial applications as well as those that make use of biochemical extracts from whole plants.

Some of these firms are dedicated to the collection of compounds on behalf of clients. Others, such as those producing phytopharmaceuticals, nutraceuticals and cosmetics include a bioprospecting activity as part of their own product value chain.

The business models of the firms involved in commercial bioprospecting in LAC countries are primarily dictated by the market focus of the firm. That is, those firms that target large pharmaceutical clients are dependent on continuous contracts with those firms in order to maintain their bioprospecting activities. Those that market their end products to retail consumers need to maintain contracts with suppliers of raw materials as part of their ongoing supply chain.

Geographical contrasts: The countries covered in this study are at different stages of development in their respective policy and regulatory frameworks for bioprospecting and biodiversity conservation. Each of the countries referenced have a particular approach to the cultivation or discouragement of commercial bioprospecting activities. The study has described how the respective national approaches and strategies are reflected in the level of support given to the research firms and commercial firms operating within their borders. The fact that there may be more bioprospecting activities in Brazil than in Mexico at this time may be both a result and a reflection of the level of clarity and consistency found in the respective policy frameworks of those two countries. Each of these countries has had experiences with highly publicized and highly controversial bioprospecting arrangements with outside entities subsequent to the CBD. However, of these two countries, only Brazil has taken the initiative to follow up with the necessary legislative and governance actions to allow the activities to continue with clearly defined guidelines.

Alliances: The alliances entered into by the local commercial bioprospecting initiatives in the LAC region include working agreements with the larger client companies and collaborations with the universities and the national and international research institutions. Although there is considerable variation in types of partnership models included among these agreements, the terms of collaboration are explicit in terms of providing for distribution of work and related benefits. Of the cases reviewed, there was no incidence of alliances among the bioprospecting firms themselves. Also, to the extent that bioprospecting companies from outside the region have established alliances and collaborations, they have been primarily with universities and research institutions.

The natural product-related laboratory and field work done at public and private research institutions in the region is of major importance to the future of commercial bioprospecting in Latin America and the Caribbean. Not only have these institutions managed to obtain funding support from government agencies and international sources, but they have also established working relationships with existing companies. These arrangements have enabled the research institutions to build up in-house capacity and appropriate technological infrastructure for purposes of participating in the value-added chain of activities involved in commercial bioprospecting. Institutional patent policies and technology transfer protocols must be made compatible with industrial liaison arrangements.

As the bioprospecting firms and related entities not only benefit from international commercial alliances but will increasingly count on them for capital infusion and market access, it will be important for national and regional policies to convey consistency and clarity in regulatory frameworks affecting bioprospecting.

Access and benefit sharing: The information reviewed in this study reinforces the observation that any inconsistent or unclear public policy positions or incomplete regulatory provisions put forth by national governments with regard to access to local genetic resources can affect the ability of bioprospecting-based firms to conduct business. Additionally, where it is unclear which groups have authorization to negotiate on behalf of the indigenous communities, the

firms and the research institutions reviewed in this study uniformly reported that they avoid dealing with bioprospecting samples that involve indigenous knowledge or indigenous lands.

Furthermore, the firms build their strategies on the generally accepted distinction which is made between "popular" knowledge and indigenous knowledge. Knowledge about medicinal value of certain herbs and plants that falls into the realm of popular knowledge is considered to be in the public domain and thus not subject to the terms which regulate access to indigenous knowledge. These same firms or institutions also limit their collection sites to non-indigenous lands. In the case of Extracta in Brazil, the collection sites are owned by private parties which are included in the eventual royalty stream. In the case of INBio in Costa Rica the collection sites are national parks and the beneficiary is the governing public agency. It is important to note that the new legislative and regulatory provisions which are being put into place are still being adjusted. These provisions invite a comprehensive overview and will require performance monitoring over the long term.

This study has pointed out how commercial firms active in this area must frequently operate in the context of an incomplete and inconsistent regulatory framework. This can often lead to irregular enforcement of laws and to problems in the area of product registration, intellectual property protection or other compliance issues. If biodiversity resources in Latin America and the Caribbean are to be exploited in a sustainable manner for the purpose of job creation and poverty alleviation, policy makers need to become familiar with the issues surrounding the creation, operation and economic viability of commercial bioprospecting firms and related enterprises in the region.

Financial challenges: Among the various financial hurdles, there is a need to change the attitudes of banking institutions to include greater understanding of the long-term development needs of bioprospecting companies and how their contributions fit into to the value chain of established industries.

Direct government financial assistance has not necessarily played a role in the establishment of the bioprospecting firms. However, many of the firms have benefited indirectly from some form of public financing. If the reason for the lack of direct financing is based on the uncertainty of the products, it is appropriate to explore approaches to providing a more comprehensive picture of how commercial bioprospecting can offer opportunities for value-added activities associated with existing industrial sectors.

By the same token, it is also important to maintain expectations at a realistic level. There are often unrealistic expectations on the part of the indigenous groups and others in the host countries regarding the actual present-day value of the particular compounds or source materials being prospected. This is especially important given the amount of resources that must be invested in the development and clinical testing of any compound prior to market entry. Out of every 10,000 compounds tested only one or two may make it to market.

Technological issues: The technological environments of the pharmaceutical, cosmetics, food sector and other target industries in which bioprospecting firms operate are rapidly advancing and require continuous monitoring and strategic adjustments on the part of the bioprospecting firms in the LAC region. Certain bioprospecting companies are having to invest in technological platforms such as high-throughput screening technologies, "super critical" extraction methods and others. The methods for maintenance of libraries of biochemical compounds, gene banks and other biological data collections also require constant updating. However, existing financial resources of the firms do not always allow these firms to stay ahead of the technological innovations, particularly in the area of molecular analysis and novel techniques for plant identification.

With regard to the use of combinatorial chemistry and other means of synthesizing target compounds, the firms and institutions reviewed for this study did not express any concern that such approaches would supplant their efforts.

Employment generation and innovation: Although the sizes of the direct bioprospecting operations themselves are relatively small, it is important to consider the employment impact of the associated companies involved. In the case of the dedicated bioprospecting firms like Extracta, it was pointed out that the direct employment in the firm is subject to the contracts at hand. In the case of companies like Natura, the overall employment numbers are much larger even though the direct bioprospecting-related activities are small. In both cases, there is a continuing potential for involving persons as gatherers of materials with the proper advance training in collection protocols.

In terms of the areas of potential growth and innovation, much will depend on if the commercial bioprospecting firms as a whole can go beyond simply exporting samples for others to process and develop. It has been argued in this study that LAC countries must continue to develop the infrastructure needed to perform value-added activities inside the region. Certain countries like Costa Rica and Brazil have made much progress in increasing both their capacity and their strategic intent in this regard. National policies that continue to support the development of human resources will be of critical importance for enabling and enhancing the needed infrastructure for commercial bioprospecting.

Expectations of economic impact must be kept realistic in accordance with all of the obstacles and considerations discussed in this report. However, it is through targeted capacity-building, continuous monitoring and creative adaptation of the national and regional policy frameworks that the innovation potential of commercial bioprospecting may be fully realized.

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