

PN ABK-919 98202

FINAL COMPENDIUM

for

A Practical Workshop on Biodiversity Prospecting for Cameroon, Madagascar and Ghana

April 24 - May 2, 1995

Organized in Costa Rica by



Organized in the United States by



Organized in Cameroon by



Bioresources Conservation and Development
Programme BDCP

*Instituto Nacional de Biodiversidad, INBio. Santo Domingo de Heredia, Costa Rica
August, 1995*

Sponsored by



with financial assistance from



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**U.S. Department of State, Oceans
and International Environmental
and Scientific Affairs**

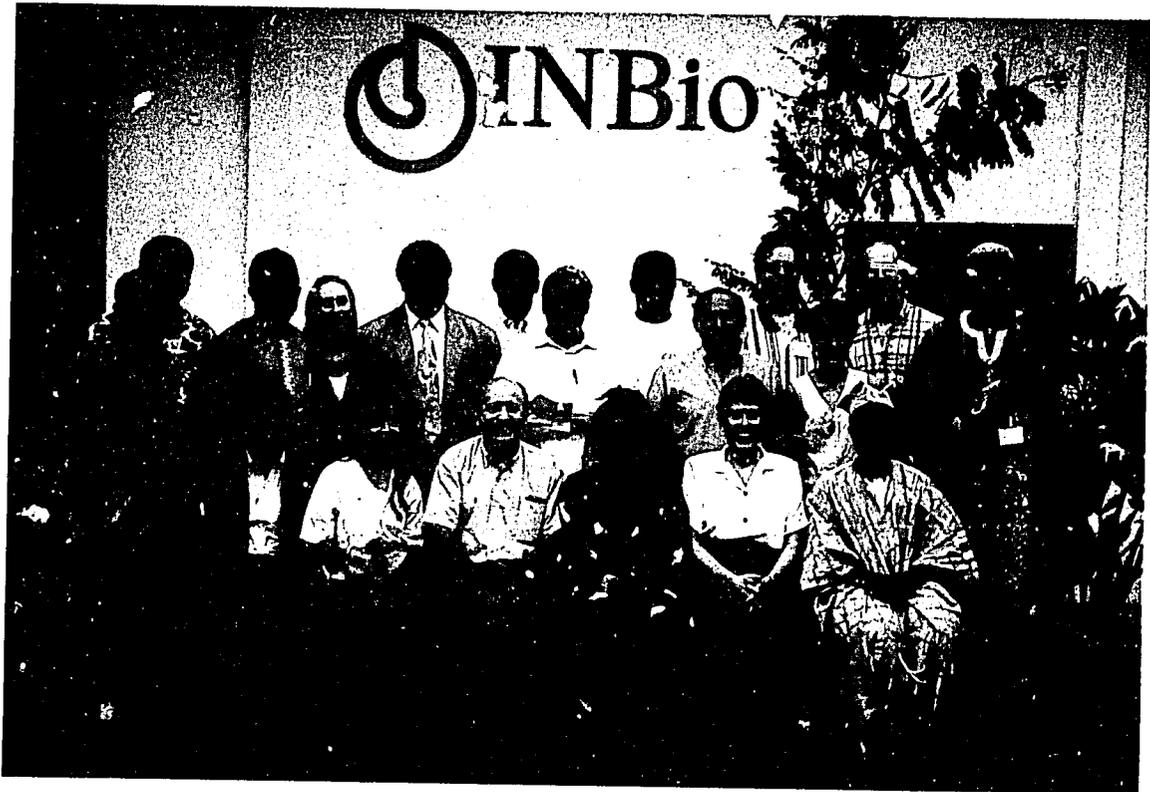
U.S. National Cancer Institute



**Biodiversity
Support
Program**

SECTION 1

INTRODUCTION



EXECUTIVE SUMMARY

On April 24, 1995, fourteen participants from the nations of Cameroon, Madagascar, Ghana and the United States met in Santo Domingo de Heredia, Costa Rica for a 9-day workshop on biodiversity prospecting. The workshop was held at the Instituto Nacional de Biodiversidad (INBio), a private, non-profit research institute dedicated to conserving Costa Rica's biological diversity. INBio presently works to inventory the country's biodiversity while searching for sustainable ways to use these resources, for conservation's benefit. The workshop was designed primarily for an audience comprised of environmental policy makers, working scientists and conservationists, in order to explore practical strategies for promoting equity in the utilization of genetic resources, a key provision of the United Nations Convention on Biological Diversity.

The principal objectives of the workshop were to share INBio's experiences in the fields of biodiversity management and prospecting along with the experiences of Bioresources Development and Conservation Programme (BDGP) in the fields of traditional knowledge and community resource management with experts from the attending nations. Major components of a bioprospecting program were discussed, among them, national policies needed to create an "enabling environment" for equitable bioprospecting, biodiversity inventory and management programs, technology access, business development, and strategies for the equitable sharing of benefits with biodiversity stakeholders including local communities. The workshop placed particular emphasis on building constructive partnerships between academic, government, private voluntary organizations and the private sector, to achieve the complementary goals of conservation and community development.

What follows is a selection of documents presented at the bioprospecting workshop. It is the intention of the editors to present this compendium as a practical tool for conservationists, scientists, rural development specialists, attorneys, business managers and policy makers as a reference guide on biodiversity prospecting. The compendium is organized by topic, e.g. national policy, scientific protocols, legal tools and so on, to reflect this eclectic mix. In all sections the editors strove to include information deemed to be of practical use, eschewing academic debate in favor of actual strategies for promoting equitable bioprospecting.

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Summary of Terms: Collaboration Agreement, INBio-Merck & Co. Inc. Rights Agreement (redacted version)

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A PRACTICAL WORKSHOP ON BIODIVERSITY PROSPECTING FOR CAMEROON, MADAGASCAR AND GHANA

April 24-May 2, 1995

Conceived by
Instituto Nacional de Biodiversidad (INBio) of Costa Rica
and
Bioresources Development and Conservation Programme (BDCP) of Cameroon and Nigeria

Organized in Costa Rica by
Instituto Nacional de Biodiversidad

Organized in Cameroon by
Bioresources Development and Conservation Programme

Sponsored by
U.S. Agency for International Development (USAID)
U.S. Department of State, Oceans and International Environmental and Scientific Affairs (OES)
World Bank
British Overseas Development Administration (ODA)
Forestry Support Program of USDA Forest Service
U.S. National Cancer Institute (NCI)
Biodiversity Support Program (BSP)

INTRODUCTION TO THE WORKSHOP COMPENDIUM

I. Background. On April 24, 1995, fourteen participants from the nations of Cameroon, Madagascar, Ghana and the United States met at the Instituto Nacional de Biodiversidad (INBio) in Santo Domingo de Heredia, Costa Rica for a 9-day workshop on conserving biological diversity through biodiversity prospecting for pharmaceutical, agrochemical and other economically valuable products from natural sources. INBio is a private, non-profit research institute dedicated to conserving Costa Rica's biological diversity, and is presently conducting an inventory of the country's biodiversity while searching for sustainable ways to use these resources. To facilitate the goal of sustainable economic uses, INBio has developed over a dozen collaborative research agreements with academia and industry.

The workshop was designed primarily for an audience comprised of environmental policy makers, working scientists and conservationists, in order to explore practical strategies for promoting equity in the utilization of genetic resources, a key provision of the United Nations Convention on Biological Diversity. The workshop placed particular emphasis on building constructive agreements between academia, government, private voluntary organizations and the private sector, to achieve the complementary goals of conservation and community development.

Principal objectives of the workshop were to share INBio experiences in the field of biodiversity management and prospecting along with the experiences of Bioresources Development and Conservation Programme (BDCP) in the fields of traditional knowledge and community resources management. BDCP is a non-profit organization founded in Nigeria with additional offices in Guinea and Cameroon which serves as a platform for a collaborating group of natural products scientists, environmentalists and industrialists aiming to elaborate conservation programs that link the development needs of people living in tropical countries with the protection of the environment.

The specific workshop objectives were designed to :

- give participants an opportunity to gain first-hand knowledge of the INBio pilot project in Costa Rica and specifically, INBio's experiences in bioprospecting;
- examine in detail BDCP projects which utilize bioprospecting with traditional knowledge to promote rural development and research on tropical diseases;
- permit the participants to weigh the feasibility of adapting or adopting the experience gained during the workshop to their own national paradigms;
- analyze Costa Rica's national policy and legal framework regarding access to, management and control of wild genetic resources;
- discuss strategies that will allow participants to successfully develop equitable bioprospecting initiatives and conserve natural resources in the participants' own countries; and
- explore the possibility of establishing a mutual assistance and information exchange network for biodiversity conservation and management in tropical countries.

These objectives were addressed through the following workshop components:

- presentations summarizing history of conservation initiatives and illustrating the institutional development of INBio in Costa Rica and BDCP in Africa;
- an overview of trade-related provisions of the U.N. Convention on Biological Diversity and a discussion of Costa Rica's legal framework for regulating access to wild genetic resources;
- close examination of INBio's Biodiversity Prospecting Program with sessions on natural-products chemistry and microbiology, bioprospecting data and management, and INBio's other programs for the national biodiversity inventory and information management and dissemination.

- case studies of INBio's strategy for private sector business development;
- a special session on commercial research contracts conducted by an attorney with Conservation International;
- a full-day session on promoting African community development and tropical disease research through bioprospecting conducted by a medical chemist and expert on traditional medicine with BDCP;
- a field trip to the Guanacaste Conservation Area to observe INBio's parataxonomist program and bioprospecting field collection techniques, as well as to observe how bioprospecting can be integrated into conservation area management; and
- a roundtable discussion of bioprospecting initiatives in the participants' home countries.

II. Assumptions. Biodiversity prospecting is a controversial subject. The editors wish to acknowledge that this workshop was designed with the following set of assumptions in mind:

- 1) Biodiversity prospecting (or "Bioprospecting") can be pursued in an equitable manner that promotes national economic development, conservation of biological diversity, and advances in the welfare of indigenous or other rural communities.
- 2) Achieving equity in bioprospecting requires the cooperation of specialists drawn from numerous disciplines, including conservation biology, botany and other taxonomic fields, ethnobotany, chemistry, medicine, microbiology, law, community development, business and government.
- 3) A practical workshop on equitable prospecting can provide suggestions for adapting a bioprospecting program to conditions found in many developing countries by combining presentations on legal and policy issues with presentations on scientific and market concerns, a discussion of community resource rights and prior informed consent, traditional knowledge and appropriate markets for it, and strategies for returning benefits to rural communities in an appropriate or culturally-sensitive manner.
- 4) INBio's bioprospecting activities are closely linked with Conservation Area management and government policy in Costa Rica, and these three areas reinforce each other to produce incentives for biodiversity conservation. INBio has been successful at redefining the scientific and business relationships between private organizations in a biodiversity-rich developing country, and academic, industrial and government research institutions of industrialized nations.

5) BDCP's bioprospecting activities are closely linked with African rural communities as well as African private industry. BDCP has been successful at identifying active constituents for traditional medicinal cures, in some cases obtaining intellectual property rights to these "phytomedicines", with the goal of developing them into commercial products for affordable health care for people living in tropical countries.

6) It is possible to learn from INBio and BDCP elements of equitable bioprospecting which are transferable to other national situations. Neither INBio nor BDCP provide models for bioprospecting but rather examples, and it is useful to consider both when designing a bioprospecting program, recognizing particular sociopolitical or socioeconomic realities of any given nation.

7) A workshop can be an opportunity to strengthen institutional ties between organizations engaged in bioprospecting. Besides INBio, which accomplished most of the organizational part of the workshop, and BDCP, which played key role in organizing Cameroonian participation, a representative of Conservation International (CI) was invited to speak at the workshop. CI is an international conservation organization with local offices worldwide, including one in Suriname engaged in a major bioprospecting project with several indigenous communities. This project is returning benefits from research and development to source communities in a manner that is culturally-sensitive and promotes economic development of the community as a whole.

8) An informal workshop is the best format for exchanging ideas about bioprospecting. In order to achieve this synthesis of science, policy, conservation and community development, and business and market development, it is most effective to present material to an audience comprised of conservationists, scientists *and* policy makers. Actual laboratory and field demonstrations at INBio's research sites in Costa Rica are more effective teaching tools than abstract lectures. Finally, an informal workshop led by actual practitioners in the field of bioprospecting, emphasizing discussions and constructive criticism of specific projects, can synthesize this information more effectively than lectures given by academics or theorists.

III. Summary of the participants conclusions on business development strategies. Throughout the workshop, participants were encouraged to discuss practical strategies for building equitable bioprospecting programs in their home countries that would yield a mixture of short-term benefits (training and voluntary technology transfer, monetary compensation, health or other community benefits) and long-term benefits (royalties, trust funds, value-adding capacity building, new treatments for tropical diseases). Because natural products research and development is a time-consuming and technology-

intensive process, it was generally agreed by participants that trading genetic resources for technology was as important as trading for monetary compensation, in order to gain means to add value to genetic resources.

A session on business development strategies to encourage voluntary trading in genetic resources and technology transfer produced the following list of conclusions developed by the workshop participants:

- 1) A fundamental step must be taken to develop a national legal framework that provides a stable "enabling environment" for bioprospecting business development, one which would allow individuals with vision and leadership to build an organization devoted to equitable prospecting. Political will on the part of the governments of biodiversity-rich nations is essential for this.
- 2) One way to build this enabling environment is for governments to set minimum standards of equity from which bioprospecting agreements can be negotiated between parties. Standards for equity should be fair and recognize the economic constraints of natural products-based firms as well as the goals set by governments for national economic development, and individual and community rights to ownership of genetic resources.
- 3) Autonomous (preferably private) bioprospecting organizations should be encouraged to comply with standards for equity set by governments while still being allowed to freely negotiate deals with private business partners. In general, private firms prefer to negotiate business deals with other private organizations.
- 4) To begin raising revenue from bioprospecting, reliable natural products supplies and research services should be developed. Such services would offer proper taxonomic identification, compliance with clear governmental policies on access to genetic resources, strict attention to obtaining prior informed consent from local communities (if sampling on communal land), and good quality control in sample preparation. These services would also offer a reliable resupply of extracts and other biological material for companies interested in pursuing further research for pharmaceutical, biotechnology, agrochemical, consumer products or other commercial applications.
- 5) Wherever possible, attempts should be made to negotiate access to technology in exchange for access to genetic resources. This would allow bioprospecting organizations to gain the means, over time, to add value to genetic resources in-country, thereby raising bioprospecting revenues.
- 6) Scientific, business and legal expertise is essential for equitable business development. For nations lacking any of these components, forming partnerships internationally is fundamental.

7) The Biodiversity Convention has built fears on the part of the private sector of industrialized nations that rules on access to genetic resources may suddenly change in any given country, thus creating a disincentive for investing in natural products research and development programs in biodiversity-rich nations. Those nations acting to address the business development strategies outlined here early on will gain a comparative advantage in attracting new natural products investment in research and development.

What follows is a selection of documents presented at the bioprospecting workshop. Several documents were prepared specifically for this workshop, while other were previously published but distributed as useful background material. These documents have been reproduced here with permission from the original publishers.

It is the intention of the organizers of this workshop to present this compendium as a practical tool for scientists, rural development specialists, attorneys, business managers and policy makers as a reference guide on bioprospecting. The compendium is organized by topic, e.g. national policy, scientific protocols, legal tools and so on, to reflect this eclectic mix. In all sections the editors strove to include information deemed to be of practical use, eschewing academic debate in favor of actual strategies for promoting equitable bioprospecting.

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Editors, Bioprospecting Workshop Compendium
May 8, 1995
Santo Domingo de Heredia, Costa Rica

WORKSHOP PROGRAM
A PRACTICAL WORKSHOP ON BIODIVERSITY PROSPECTING FOR
CAMEROON, MADAGASCAR AND GHANA
April 22-May 3

DATE	HOUR	ACTIVITY	DETAIL
April 22		Participants Arrive in Costa Rica	

April 23		Day for Recuperation	
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April 24 (INBio)	7:30 a.m.	Transfer to INBio	
	8:00 a.m.	Opening Ceremony	
	9:20 a.m.	Coffee Break	
	9:45 a.m.	"Natural History of Costa Rica and the Conceptual Evolution of the Conservation Areas"	Dr. Carlos Valerio
	11:00 a.m.	"Costa Rica's Economic Framework: Natural resource usage and its impact in Costa Rica"	Dr. Alvaro Umaña
	12:30 p.m.	Lunch	
	2:00 p.m.	"National Sovereignty, Property Rights and the Convention on Biological Diversity" (including international trade regimes)	Dr. Jorge Cabrera
	3:40 p.m.	Coffee Break	
	4:00 p.m.	"The Legal Framework for Biodiversity Management and Prospecting in Costa Rica"	Lic. Carlos Manuel Rodríguez
	5:30 p.m.	Discussion Session	
	6:30 p.m.	Reception with INBio Personnel	
	8:00 p.m.	Return to Hotel	

April 25 (INBio)	7:30 a.m.	Transfer to INBio	
	8:00 a.m.	"Save, Know and Use: INBio's genesis and institutional development"	Dr. Rodrigo Gámez
	9:45 am.	Coffee Break	
	10:00 a.m.	Biodiversity Inventory Program "Methodology, social and economic effects in Costa Rica" • Arthropod Reference Collection • Botany Reference Collection • Malacology Reference Collection	Dr. Jorge Jiménez
	12:00 p.m.	Discussion Session	
	12:30 p.m.	Lunch	

DATE	HOOR	ACTIVITY	DETAIL
April 25 (INBio)	1:30 p.m.	INBITTA	Carlos Mario Rodríguez
	2:00 p.m.	Discussion Session	
	2:30 p.m.	Inventory Program Continued • Inventory Information Management	Felipe Oñoro and Allan Prendas
	3:30 p.m.	<i>Coffee Break</i>	
	4:00 p.m.	Biodiversity Information Management Program • Biodiversity Information Management System • Geographic Information System • Multimedia • Internet	Herbert Barrientos, Marco Castro, Verónica Sancho and Werner Bohl
	6:00 p.m.	Discussion Session	
	6:30 p.m.	Return to Hotel	

April 26 (INBio)	7:30 a.m.	Transfer to INBio	
	8:00 a.m.	Biodiversity Prospecting Frameworks: "Methodologies and Collaborative Agreements: Case studies of INBio's private sector collaborations"	Dr. Ana Sittenfeld
	10:00 a.m.	<i>Coffee Break</i>	
	10:20 a.m.	Chemical Prospecting Laboratory	Dr. Giselle Tamayo
	11:20 a.m.	Bioprospecting Plant Collection: Methodology and field collection	María Auxiliadora Mora, Nora Martín, Dr. Giselle Tamayo
	12:00 p.m.	<i>Lunch</i>	
	1:30 -4:00 p.m.	GROUP A	GROUP B
		Inside the Chemical Prospecting Laboratory (two groups)	
	1:30 p.m.	Plant collection	Bioscreening
	2:30 p.m.	<i>Coffee Break</i>	
	3:00 p.m.	Natural Products Lab	Plant collection
	4:00 p.m.	Bioscreening	Natural Products Lab
	5:00 p.m.	Biodiversity Prospecting Database (María Auxiliadora Mora)	
	5:30 p.m.	Discussion Session	
	6:00 p.m.	Return to Hotel	

April 27 (INBio)	7:30 a.m.	Transfer to INBio	
	8:00 a.m.	Bioassays	Dr. Misael Chinchilla Dr. José Ma. Gutiérrez Dr. José Bonilla
	8:25 a.m.	• Malaria	
	8:50 a.m.	• Phospholipases A2 • HIV- BIV	
	9:15 a.m.	<i>Coffee Break</i>	
	9:30 a.m.	"The Market for Biological & Genetic Resources and the Pharmaceutical Industry"	Dr. Daniel Putterman

DATE	HOUR	ACTIVITY	DETAIL
	10:30 p.m.	"Overview of Contract Law, Material Transfer Agreements and Intellectual Property Law, Including Trade Secrets and Intellectual Property Protection for Traditional Knowledge"	Dr. Marianne Guerin-McManus
	12:30 p.m.	Lunch	
	1:15 p.m.	Return to Hotel Afternoon free	

April 28 (Santa Rosa)	8:00 a.m.	Departure for Guanacaste	
	12:00 m.	Lunch	ACG
	1:30 p.m.	Introduction to the GCA Pilot Project	Sigifredo Marín
	3:00 p.m.	Coffee Break	ACG
	3:20 p.m.	INBio's Inventory Activities: "The Parataxonomists Field Work"	Róger Blanco and parataxonomists
	6:00 p.m.	Dinner	ACG
	8:00 p.m.	Introduction to the Prospecting Field Work : Insect collection • Presentation of personnel, basic equipment, sites and criteria for collecting specimens • Visit to the light traps	Felipe Chavarría, Vanessa Nielsen, Isabel Salas, Sandy Salas

April 29 (Santa Rosa)	6:30 a.m.	Breakfast	ACG
	8:00 a.m.	Prospecting Field Work I: Botany collection	Nelson Zamora, Nora Martín
	11:30 a.m.	Lunch	ACG
	1:00-5:30 p.m.	GROUP A	GROUP B
		Prospecting Field Work II: Entomology collection (two groups)	
	1:00 p.m.	Insect collection: • Details of collection, including limitations in traditional entomological collecting, site, methodologies, and manipulation of specimens in the field	Insect collection: • Details of collection, including limitations in traditional entomological collecting, site, methodologies, and manipulation of specimens in the field
	3:00 p.m.	Coffee Break	
	3:30 p.m.	Specimens and information Management • Manipulation, separation, mounting, labelling and preliminary identification of specimens • Insect breeding • Butterflies, coleoptera	Specimens and information Management • Manipulation, separation, mounting, labelling and preliminary identification of specimens • Insect breeding • Butterflies, coleoptera

DATE	HOUR	ACTIVITY	DETAIL
	5:30 p.m.	Discussion Session	
	6:00 p.m.	Dinner	ACG
	7:30 p.m.	INBio's Biodiversity Information Dissemination Program • Public relations and educational outreach	Elvira Sancho

April 30	6:30 a.m.	Breakfast	ACG
	8:30 a.m.	Departure for San José	
	12:00 p.m.	Lunch (on the road)	
	1:30 p.m.	Return to Hotel - Afternoon Free	

May 1 (INBio)	7:30 a.m.	Transfer to INBio	
	8:00 a.m.	Returning Benefits to Local Communities I: "The Forest People's Fund of Surinam"	Dr. Marianne Guerin-McManus
	9:00 a.m.	"The Commercial Potential of Traditional Knowledge"	Dr. Maurice Iwu
	10:30 a.m.	Coffee Break	
	10:50 a.m.	Returning Benefits to Local Communities II: "Using Biodiversity Prospecting to Develop Low-cost Phytomedicines"	Dr. Maurice Iwu
	12:15 p.m.	Lunch	
	2:00 p.m.	"Biodiversity Prospecting in Africa with an Overview of the Bioresources Development and Conservation Programme"	Dr. Maurice Iwu
	3:30 p.m.	Coffee Break	
	4:00 p.m.	Continuation of BDCP Overview	Dr. Maurice Iwu
	5:00 p.m.	Discussion Session	
	5:30 p.m.	Return to Hotel	

May 2 (INBio)	7:30 a.m.	Transfer to INBio	
	8:00 a.m.	Individual Country Presentations on Bioprospecting Science and Policy • Cameroon • Madagascar • Ghana • U.S.A. (Dr. Robert Szaro)	Speakers to be announced
	10:00 a.m.	Coffee Break	

DATE	HOUR	ACTIVITY	DETAIL
	10:20 a.m.	Round Table Discussions with INBio's Directors Director General Deputy Director Inventory Director Prospecting Director Dissemination Program Information Program	Dr. R. Gámez Dr. A. Piva Dr. J. Jiménez Dr. A. Sittenfeld
	12:30 p.m.	Lunch	
May 2 (INBio)	1:30 p.m.	Conclusions & Recommendations	
	3:30 p.m.	Coffee Break	
	3:50 p.m.	Evaluation	
	5:00 p.m.	Return to Hotel	
	7:00 p.m.	Closing Dinner	

May 3		Participants Depart Costa Rica	
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*"A Practical Workshop on Biodiversity Prospecting for
Cameroon, Madagascar, and Ghana"*

INBio
Santo Domingo de Heredia, Costa Rica
April 22 - May 3, 1995

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COORDINATION IN COSTA RICA

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SUMMARY OF THE PARTICIPANTS' EVALUATION OF THE WORKSHOP

On the last day of the workshop an evaluation form, reproduced on the following pages, was distributed to the participants to collect anonymous comments on the effectiveness of the workshop. Numerical results were tabulated and the mean values presented here:

Sample Size: 14 (7 participants from Cameroon, 3 from Madagascar, 2 from Ghana, 2 from U.S.A.)

Scale: 1 to 5 (1 = strongly satisfied; 5 = strongly dissatisfied)

TECHNICAL ASPECTS

A. Please comment on the following workshop methodology, objectives and presentations:

1. Did the workshop achieve its proposed objectives?
average score = 1.2
2. Do you feel that the workshop methodology was satisfactory?
average score = 1.4
3. Do you consider that the methodology allowed for adequate discussion and exchange of ideas and concepts?
average score = 1.4
4. Was the reference material provided useful to the topics covered?
average score = 1.1
5. Will you make use of the reference material provided when you return to your country?
average score = 1.4
6. Do you feel that the individuals involved in the workshop presentations commanded sufficient knowledge of the topics covered? Was their expertise made available to you?
average score = 1.2
7. Did the quality and topics presented by the invited *national* speakers meet your expectations? Were the topics covered relevant to the workshop agenda?
average score = 1.3
8. Did the quality and topics presented by the invited *international* speakers meet your expectations? Were the topics covered relevant to the workshop agenda?
average score = 1.5
9. Do you feel that the country presentations and the round table sessions were valuable to the workshop process?
average score = 1.7

B. Please comment on INBio's four basic programs and other components including the laboratory exercises and the GCA field trip:

10. Do you feel that the information provided about the National Biodiversity Inventory Program was both relevant and sufficient in scope?
average score = 1.2
11. Do you feel that the information provided INBio's Information Management Program was both relevant and sufficient in scope?
average score = 1.7
12. Do you feel that the information provided about INBio's Information Dissemination Program was both relevant and sufficient in scope?
average score = 1.4
13. Do you feel that the prospecting laboratory component allowed you to understand the chemical processes involved in INBio's Biodiversity Prospecting Program?
average score = 1.6
14. Do you feel that the Guanacaste Conservation Area component enabled you to obtain a clear idea of the National System of Conservation Areas and the internal operations of the Guanacaste Conservation Area in particular?
average score = 1.6
15. Do you feel that the Guanacaste Conservation Area component enabled you to obtain a clear idea of the fieldwork involved in INBio's National Biodiversity Inventory Program?
average score = 1.3
16. Do you feel that the Guanacaste Conservation Area component enabled you to obtain a clear idea of the fieldwork involved in INBio's Biodiversity Prospecting Program?
average score = 1.2

LOGISTICAL ASPECTS

17. Please comment on the following:

- | | |
|--------------------------|----------------------------|
| Accommodations: | average score = 1.3 |
| Meals: | average score = 1.4 |
| Ground transportation: | average score = 1.0 |
| Logistical coordination: | average score = 1.4 |

SECTION 2

INTERNATIONAL BIODIVERSITY PROSPECTING POLICY AND COSTA RICA

SECTION 2: INTERNATIONAL BIOPROSPECTING POLICY IN COSTA RICA

Introduction:

In this section, examples of how Costa Rica regulates access to genetic resources are presented. The government's relationship to INBio is defined here, as is government policy towards requests for permits for collecting samples of biodiversity from public lands. This section presents one example of an equitable relationship between a national government and a private, non-profit organization that conducts bioprospecting, and a national biodiversity inventory, among other activities. In this relationship, and as a private organization, INBio negotiates agreements with national and foreign partners to research Costa Rican genetic resources (located in protected areas), while ensuring that the maximum benefit will accrue to the nation as a whole.

Excerpts from the Biodiversity Convention relating to equity in the development of genetic resources are presented first in this section, as is a statement interpreting these clauses published by the U.S. government. The interpretation of these clauses by many Northern governments is roughly in accord with that of the United States. Following this are a series of articles exploring the legal issues governing the use of biodiversity in Costa Rica, including bioprospecting and the relationship between INBio and the Costa Rican Ministry of Natural Resources, Energy and Mines (MIRENEM). These articles are followed by copies of the relevant Costa Rican laws defining biodiversity property rights, as well as a copy of the Cooperative Agreement between INBio and MIRENEM. Following these are copies of the permits necessary for any individual or group, including INBio, to collect biodiversity samples from Costa Rica's publicly protected areas.

Contents: Section 2

Convention on Biological Diversity (excerpts)

Interpretive Statement of the United States Government on the U.N. Convention on Biological Diversity (excerpts)

The Legal Basis of Biodiversity Use in Costa Rica. By Jorge Alberto Cabrera Magdalia (reprinted with permission)

Costa Rican Law of Conservation of Wildlife, Articles: 1; 3; 4; 5; 17; 36, 37 & 50.

Legal Issues: Contracts, Intellectual and Other Property Rights. By Carlos Manuel Rodríguez Echandi

Cooperative Agreement Between the Costa Rican Ministry of Natural Resources, Energy and Mines and the National Biodiversity Institute (INBio) Association

Permits for Collecting Biological Materials in Costa Rican Protected Areas

1. Permission for Investigation and Research
2. Research Activity Registration Form
3. Payment Voucher in Favour of the Government of Costa Rica
4. Resolution N° 245.94.DER

Additional Reading: Section 2

- Ayad, W.G. 1994. The CGIAR and the Convention on Biological Diversity. *In* Krattiger, *et al* (eds.). *Widening Perspectives on Biodiversity*. Geneva: IUCN, Gland and the International Academy of the Environment.
- Barton, J.H. 1994. Ethnobotany and Intellectual Property Rights. *In* *Ethnobotany and the Search for New Drugs: Ciba Foundation Symposium 185*. Chichester: John Wiley & Sons.
- Gollin, M.A. 1993. An Intellectual Property Rights Framework for Biodiversity Prospecting. *In* Reid, W., *et al*, (eds.). *Biodiversity Prospecting: Using Genetic Resources for Sustainable Development*. Washington D.C.: World Resources Institute.
- Lesser, W. 1994. Institutional Mechanisms Supporting Trade in Genetic Materials: Issues Under the Biodiversity Convention and GATT/TRIPS. *Environment and Trade Series No. 4*. Geneva: United Nations Environment Programme.
- Mugabe J. & C. Juma. 1994. *Technology Development and the Convention on Biological Diversity*. Nairobi: African Centre for Technology Studies.
- Posey, D. 1991. Effecting International Change. *Cultural Survival Quarterly*, Summer:29-35.
- Putterman, D.M. 1994. Trade and the Biodiversity Convention. *Nature* 317:553-4.
- The Melaka Accord. 1994. Resolutions ratified by the Eighth Asian Symposium on Medicinal Plants, Spices, and Other Natural Products (ASOMPS VIII), Melaka, Malaysia, June 12-16.

EXCERPTS FROM THE CONVENTION ON BIOLOGICAL DIVERSITY

(August 1992 Version, elaborated by the Earth Council)

Article 1. Objectives

The objectives of this Convention, to be pursued in accordance with its relevant provisions, are the conservation of biological diversity, the sustainable use of its components and the fair and equitable sharing of the benefits arising out of the utilization of genetic resources, including by appropriate access to genetic resources and by appropriate transfer of relevant technologies, taking into account all rights over those resources and to technologies, and by appropriate funding.

Article 3. Principle

States have, in accordance with the Charter of the United Nations and the principles of international law, the sovereign right to exploit their own resources pursuant to their own environmental policies, and the responsibility to ensure that activities within their jurisdiction or control do not cause damage to the environment of other States or of areas beyond the limits of national jurisdiction.

Article 15. Access to Genetic Resources

1. Recognizing the sovereign rights of States over their natural resources, the authority to determine access to genetic resources rests with the national governments and is subject to national legislation.
2. Each Contracting Party shall endeavour to create conditions to facilitate access to genetic resources for environmentally sound uses by other Contracting Parties and not to impose restrictions that run counter to the objectives of this Convention.
3. For the purpose of this Convention, the genetic resources being provided by a Contracting Party, as referred to in this Article and Articles 16 and 19, are

only those that are provided by Contracting Parties that are countries of origin of such resources or by the Parties that have acquired the genetic resources in accordance with this Convention.

4. Access, where granted, shall be on mutually agreed terms and subject to the provisions of this Article.
5. Access to genetic resources shall be subject to prior informed consent of the Contracting Party providing such resources, unless otherwise determined by that Party.
6. Each Contracting Party shall endeavour to develop and carry out scientific research based on genetic resources provided by other Contracting Parties with the full participation of, and where possible in, such Contracting Parties.
7. Each Contracting Party shall take legislative, administrative or policy measures, as appropriate, and in accordance with Articles 16 and 19 and, where necessary, through the financial mechanism established by Articles 20 and 21 with the aim of sharing in a fair and equitable way the results of research and development and the benefits arising from the commercial and other utilization of genetic resources with the Contracting Party providing such resources. Such sharing shall be upon mutually agreed terms.

Article 16. Access to and Transfer of Technology

1. Each Contracting Party, recognizing that technology includes biotechnology, and that both access to and transfer of technology among Contracting Parties are essential elements for the attainment of the objectives of this Convention, undertakes subject to the provisions of this Article to provide and/or facilitate access for and transfer to other Contracting Parties of technologies that are relevant to the conservation and sustainable use of biological diversity or make use of genetic resources and do not cause significant damage to the environment.
2. Access to and transfer of technology referred to in paragraph 1 above to developing countries shall be provided and/or facilitated under fair and most favourable terms, including on concessional and preferential terms where mutually agreed, and, where necessary, in accordance with the financial mechanism established by Articles 20 and 21. In the case of technology subject to patents and other intellectual property rights, such access and transfer shall be provided on terms which recognize and are consistent with the adequate and effective protection of intellectual property rights. The application of this paragraph shall be consistent with paragraphs 3, 4 and 5 below.

3. Each Contracting Party shall take legislative, administrative or policy measures, as appropriate, with the aim that Contracting Parties, in particular those that are developing countries, which provide genetic resources are provided access to and transfer of technology which makes use of those resources, on mutually agreed terms, including technology protected by patents and other intellectual property rights, where necessary, through the provisions of Articles 20 and 21 and in accordance with international law and consistent with paragraphs 4 and 5 below.

4. Each Contracting Party shall take legislative, administrative or policy measures, as appropriate, with the aim that the private sector facilitates access to, joint development and transfer of technology referred to in paragraph 1 above for the benefit of both governmental institutions and the private sector of developing countries and in this regard shall abide by the obligations included in paragraphs 1, 2 and 3 above.

5. The Contracting Parties, recognizing that patents and other intellectual property rights may have an influence on the implementation of this Convention, shall cooperate in this regard subject to national legislation and international law in order to ensure that such rights are supportive of and do not run counter to its objectives.

Article 17. Exchange of Information

1. The Contracting Parties shall facilitate the exchange of information, from all publicly available sources, relevant to the conservation and sustainable use of biological diversity, taking into account the special needs of developing countries.

2. Such exchange of information shall include exchange of results of technical, scientific and socio-economic research, as well as information on training and surveying programmes, specialized knowledge, indigenous and traditional knowledge as such and in combination with the technologies referred to in Article 16, paragraph 1. It shall also, where feasible, include repatriation of information.

EXCERPTS FROM THE
**INTERPRETIVE STATEMENT OF THE UNITED STATES
GOVERNMENT ON THE U.N. CONVENTION ON
BIOLOGICAL DIVERSITY**

“The Department of State recommends that the following understanding be included in the United States instrument of ratification [of the U.N. Biodiversity Convention]:

“It is the understanding of the Government of the United States of America with respect to provisions addressing access and transfer of technology that:

- a. **'fair and most favorable terms' in Article 16(2) means terms that are voluntarily agreed to by all parties to the transaction;**
- b. with respect to technology subject to patents and other intellectual property rights, Parties must ensure that any access to and transfer of technology that occurs recognizes and is consistent with the adequate and effective protection of intellectual property rights, and that Article 16(5) does alter this obligation." (emphases added)

“It is the understanding of the Government of the United States of America with respect to provisions addressing the conduct and location of research based on genetic resources that:

- a. Article 15(6) applies only to scientific research conducted by a Party, while Article 19(1) addresses measures taken by Parties regarding scientific research conducted by either public or private entities;
- b. Article 19(1) cannot serve as a basis for any Party to unilaterally change the terms of existing agreements involving public or private entities."

Quoted from the "Letter of Submittal" to the President, U.S. Department of State, Washington, D.C. November 16, 1993.

"Economic incentives will help all Parties achieve the environmental benefits of conservation and sustainable use of biological diversity. The Administration thus supports the concept that benefits stemming from the use of genetic resources should flow back to those nations that act to conserve biological diversity and provide access to their genetic resources. We will strive to realize this objective of the Convention.

"As recognized in the Convention, the adequate and effective protection of intellectual property rights is another important economic incentive that encourages the development of innovative technologies, improving all Parties' ability to conserve and sustainably use biological resources. **The Administration will therefore strongly resist any actions taken by Parties to the Convention that lead to inadequate levels of protection of intellectual property rights**, and will continue to pursue a vigorous policy with respect to the adequate and effective protection of intellectual property rights in negotiations on bilateral and multilateral trade agreements." (emphasis added)

Quoted from the "Letter of Transmittal" to the U.S. Senate, President William J. Clinton, The White House, November 19, 1993.

The Legal Basis of Biodiversity Use in the Republic of Costa Rica

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Introduction

There is increasing awareness at present of the economical potential of genetic resources. The emergence of so-called "third generation" biotechnology has opened the doors of a new era for research and development that has re-vitalised the economic value of biodiversity. This has taken place parallel to the alarming disappearance of flora and fauna. Legislation still lacks adequate property rights protection and the power to determine uses for this new "green gold". This paper outlines the constitutional and legal framework that determines to whom the wealth of biological diversity in Costa Rica belongs, and who will be the beneficiaries of its commercialisation. This latter point implies the existence of a legal structure that will establish the rights of indigenous communities and peasants over biological diversity—what the Food and Agriculture Organisation (FAO) of the United Nations refers to as "Farmers' rights".

The ideas presented here constitute an interpretative work, and analyse a controversial topic. These interpretations and ideas are, of course, not the only option, although they are perhaps closer than many to the majority interest.

The Wildlife Conservation Law of Costa Rica

It is particularly relevant to refer to this legislation for two essential reasons. First, this law attempts to define rights to wildlife as property, and how such property may be utilised. It also sets out the existing legal structure with regard to biodiversity, within the framework of the Constitution of the Republic of Costa Rica. Second, the legislative process was made with the total awareness of the importance of, and problems related to, determining a legal structure surrounding biodiversity, with particular attention to international contracts.

Article 3 of the Law reads: "Wildlife is declared to be in the public domain, which constitutes a natural renewable resource that forms part of the national patrimony. Thus, it is declared to be in the *public interest*: wildlife conservation, research and development of genetic species, races and genetic varieties, as well as all the wild species and varieties of wildlife brought into the country, have undergone genetic modifications in the process of adapting to diverse ecosystems" (emphasis added).

Particularly relevant are also Articles 4 and 50: "The production, management, extraction, commercialisation, and use of genetic material, of wild plants and animals, their parts, products and sub-products, are declared to be of public interest and part of the national patrimony. The control of the activities are the responsibility of the Ministry of Natural Resources, Energy and Mines (MIRENEM); thus, the Ministry is granted the right to extend concessions to individuals under terms and conditions that favour the national public interest through public licences and according to the conditions of the present law and its regulations" (Article 4). "All research and development activities which are carried out with the intention of finding new varieties, hybrids, pharmaceutical or any other product that is a derivative of wild species and their parts, products and sub-products, must be authorised by the General Administration of Wildlife of MIRENEM, which has the authority to reject any solicitation contrary to the public interest. It is the Ministry's duty to provide a budget for carrying out these activities, and in so doing, it may use the knowledge and newly-created hybrids to develop programmes in the national interest" (Article 50).

From the legal text cited, a series of judiciary consequences may be drawn:

- wildlife is declared to be in the public domain, and of importance to the National Public Patrimony;
- wild plants, on the other hand, are declared as only of public interest and, as such, are of less importance to the National Public Patrimony;
- different judicial treatment is given under the Law for wild plants and wildlife, although genuine technical reasons for this do not justify this discrimination;
- the production, management, extraction, commercialisation, industrialisation and use of genetic material is declared to be of public interest. However, these processes are said to form part of the National Patrimony. Note how, in accordance with the declaration of National Patrimony, this material is brought under a special regime for its control by public authorities; and
- the activities mentioned above remain under a system of concession, and not simply of permission. It is in this same sense, given technical imprecision, that one must understand Article 50 of the Law (see below).

Legislative History and Interpretive Aspects

Since 1986, when discussions on the Wildlife Conservation Law began, and up until its definitive approval by the Assembly, many different modifications were presented and discussed. While a chronological and political analysis of this is of interest, it is not directly relevant to this paper.

In 1992, different interpretations of the law became central points of dispute, particularly Articles 3, 4 and 50, resulting in various opinions within the Commission studying the Project. After review by the Constitutional Court the following was established:

Article 3: *Fauna and wild plants* are declared as part of the *public domain*, and constitute a renewable natural resource which forms part of the *National Patrimony*."

Article 4: "The production, management, extraction, commercialisation, industrialisation and use of genetic material from wild flora, fauna, and seeds, are declared to be of public interest and part of the National Patrimony. Patents over them cannot be granted. The State holds the exclusive right to commercialisation of

genetic resources and the General Administration of Wildlife of MIRENEM will hold the power to grant concessions to do so. The foregoing - except for concessions extended by the said Administration - will stipulate the terms of this law and their regulation."

Article 50 was not further modified, except the final phrase in which the contractees were obliged to facilitate technology transfer and the necessary knowledge for MIRENEM to develop programmes in the national interest was suppressed.

Regarding the revision of the law, Article 50 note that "all of those activities for research and development that are carried out with the goal of obtaining new varieties or hybrids from natural species must receive corresponding authorisation by the respective offices. In order to carry out such activities, approval must be sought from the General Administration of MIRENEM, which reserves the right to reject any solicitation not in the public interest. Also, the State reserves the right to use the knowledge and new productions to develop programmes in the national interest, thus making it obligatory for the Contracting Parties to facilitate technology transfer and the necessary knowledge to carry out these programmes."

The manner in which these items were dealt with is constitutional. It developed the concept of *the Nation's own property* covered by Article 121.14 of the Constitution as well as the concept of *natural beauty* mentioned in Article 89. It was thus recognised that the notion of *National Patrimony* was correctly dealt with in the Articles cited above, and that this definition must be attributed to all of the biodiversity in Costa Rica, and not only to wild fauna.

Such conclusions also help in the consultations carried out by the government on the constitutionality of the project. This jurisdictional organ considered that the lines cited in Articles 3, 4 and 50 are in no way opposed to the Magna Carta. On the contrary, it further supported the fact that, ultimately, wild flora and fauna constitute "...the base to maintain the environment in a society." Thus, Article 89 of the Magna Carta is sufficiently broad to interpret biodiversity as being *within the concept of natural beauty*.

Nevertheless, after the consultations mentioned above, the project was returned to the Commission where it underwent a series of important modifications. In addition to the variations introduced to the text regarding other possibilities, still more changes were added. Apart from those already mentioned, final versions of Articles 3, 4 and 50 were drawn up. In this way, plants (Article 3) were eliminated from the definition of "public domain," and MIRENEM's exclusive dominion over commercialisation abroad of biodiversity (Article 4) and its right to grant patents (among others) were suppressed.

It is obvious that one result of the law project consultation was the full adjustment of the Constitution. It is not considered to have violated any Supreme Court norms, since stipulations are limited to the legalities (a regular principle for jurisprudence), contained within Articles 89 and 121.14 of the Constitution. Thus, the control and disposition of our rich biodiversity remains in the hand of the Costa Rican State, in accordance with the criteria of the national interest.

The Constitution of Costa Rica and Biodiversity

Article 89: "Cultural objectives for the Republic. Among the cultural objectives for the Republic are: the *protection of its natural beauty*, the conservation and development of the historic and artistic patrimony of the Nation, and assisting in private initiatives for scientific and technological progress. From reading the Acts of the Constitutional Assembly of 49, it can be understood that those assembled meant that "...this type of riches must remain under the protection of the State."

It is understandable that the above-cited precept does not expressly refer to biodiversity or natural resources in Costa Rica if we consider the era in which these

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concepts were being discussed, the historic social frame of reference, and the later development of scientific research in this field.

Considered from a chronological point of view, the evolution of these concepts makes sense. In the 1940s one spoke of "natural beauty" when alluding to a series of properties of natural diversity within which were included wild plants and animals. This is demonstrated in the language used for international conventions of the time, to which we will refer later. Thus it is not odd that our Constitutional Policy, referred to in Article 89, in accordance with ideas common at the time, accepted this notion of "natural beauty."

In the 1960s and 1970s wild plants and animals were described by the term "nature," which replaced the old term "natural beauty." In the 1980s yet another new designation appeared on the scene: biological diversity, or biodiversity.

The Convencion Centroamericana para la Conservacion de la Biodiversidad e Proteccion de Areas Silvestres prioritarias en America Central (Central American Convention for the Conservation of Biodiversity and Priority Wildlands Protection in Central America) signed by Central American countries on 5 June 1992, incorporates the following definitions:

Biodiversity: "All the species of flora and fauna or other living organisms, their genetic variability and the ecological systems of which they form a part."

Genetic Material: "Any material of plant, animal, micro-organism or other origin that contains functional units of hereditary information."

The Convention on Biological Diversity, signed (by over 150 nations, including Costa Rica) at the United Nations Conference on Environment and Development (UNCED) contains similar concepts:

Biological Diversity: "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."

Biological Resources: "Includes genetic resources, organisms or parts thereof, populations or any other biotic component of ecosystems with actual or potential use for humanity."

Additionally, both Conventions signal an important concept: that of the right of States to exploit their own biological resources.

The definitions cited demonstrate the evolution of terms and the necessary adaptation of constitutional precepts of such terms. We no longer speak of "natural beauty" or of "nature;" instead, other terms are used which similarly attempt to protect the same material. All of this is simply the necessary result of changing economic, social and scientific conditions. For example, initially it was considered that there were two kingdoms (flora and fauna), but now we talk of five or even six. This indicates that an adequately evolutionary method of terminology should be used to allow not only for today's classifications, but also for the direction that Costa Rica has taken in the care and protection of the environment in general, and the biodiversity of the nation in particular. This attitude is the result of the Central American Convention which is likely to be ratified by Costa Rica shortly. Finally, one must conclude that Article 89 considers within its text biodiversity itself, indicating that its care is an obligation of the State, and a consideration that cannot be ignored when drawing up judicial norms, as this would be contrary to this mandate.

The second of the constitutional norms is directly related to the constitutional foundation that Articles 3, 4 and 50 set out in the early version. Article 121.14 of the Magna Carta establishes as exclusive, attributed to the Legislative Assembly: "A decree or application of the Nation's own property" The second paragraph of this Article determines what property cannot be allowed to permanently leave the State's domain,

and that which can only be exploited by public administration, by individuals according to the law, or by special concession extended for a limited time within conditions and stipulations established by the Legislative Assembly (paragraph three).

Article 140.19 establishes the responsibilities which the President and the Ministry must assume: "Undertake administrative contracts not found in Article 121.14 of this Constitution, allowing submission first to the Legislative Assembly when exemption of taxes or quotas are stipulated, or when their objective is the exploitation of natural resources or wealth of the State."

The first of these articles establishes a transcendental juridical concept: that of *property rights of the Nation*. It is necessary to clarify what this expression means and what it includes. The acts of the Constitutional Assembly and the jurisprudential references to property rights of the nation are few, as recognised by the General Procurators of the Republic by pronouncement C-031-90 of 5 March 1990, and it is difficult to clarify such concepts. The article in question is imprecise and confusing in its regulation of the constitutional regimen for property in the public domain that forms part of the public patrimony of the Nation. It purports to speak of all of those properties which, for reasons of sovereignty or security, belong to the State, which might eventually have control over them and of some "limited genuine rights" for individuals. All of these properties within the public domain are characterised as "imprescriptable" inalienable, without embargo, and not susceptible to private appropriation.

This concept comprises all of the properties which, because of their nature or by legal deposition, are destined for public use. They are within a constitutional regimen for the public domain that determines not only property but also the possibilities to dictate their control and direction by the State. According to Article 261 of the Civil Code, and by the doctrine outlined, there are two categories of public property: those with intrinsic value, and those affected **by consideration of the Laws**.

On this point it has been written: "Classically, property in the 'public domain' includes a grouping of properties whose patent characteristics exclude their privatisation because this would be incompatible with the common usage... thus, the Law sees it as natural, and in agreement with legal principles, that they be extracted from the Civil Code. Mines, water, etc. are classic examples. Practically speaking, it is about things that are manifestations of [the State's] sovereignty or that are essential for posterity, inherent in the administration. In some opposing situations, the properties are found to be artificially affected because their existence is suitable [only] for certain uses."

The dispute becomes a question of determining the nature of Property Rights of the Nation, as referred to biodiversity, which constitutes one of the most patent manifestations of national sovereignty, and therefore remains within Article 6 of the Constitutional Policy: "[The State]... also exercises a special jurisdiction over seas adjacent to its territories up to a limit of two hundred miles, measured from the land line, with the object to *protect, conserve, and exploit exclusively the resources and natural wealth* existing in the waters, soils and sub-soils of these zones..."

If it is clear that this Article refers to natural riches located in a certain geographic zone, then this is all the more reason for the State to have an obligation in all of the national territory.

Within the national property rights referred to in the first paragraph of Article 121.14 of the Founding Charter, biodiversity is a natural wealth—so much so that it has been called "Green Petroleum" or "Green Gold". Without doubt it is a wealth over which sovereignty should be maintained and which constitutes part of the public domain of the State. Even more important is the fact that in spite of its small area, Costa Rica possesses around 5% of the world's biodiversity. Thus, the constitution defines property rights of the Nation as property characterised as being in the Public Domain, and it is subject to the same regimen as similar property.

This type of property, even when it is in private hands, is not subject to deposition by individuals: "It must be emphasised that circumstances which recognise a property in the soil or sub-soil are distinct from the civil [law] established for the surface. This does not mean that the principle of civil rights extends to the property below the surface to its full depth and into space through the air, because it is legislative practice to establish exceptions to this principle in the interim (in this case) from the mining law.

The **General Procurator of the Republic** has recognised the character of property within the Public Domain for mining rights. In fact, the same reasons brought us to determine how National property rights exist for biodiversity, authorised by judicial decree in Articles 6, 89, 121.14 and 140.19 under the Constitutional Policies.

The nature and characteristics of biodiversity guarantee its incompatibility with a regimen of private domain, since its indiscriminate exploitation would mean the loss of natural wealth of incalculable value for the nation. If there are reasons that have justified privatisation—to mining, hydrocarbons, etc.—the same arguments must be valid in placing biodiversity under a regime of public domain. That is, the same situation should bring about the same solution. Old criteria do not imply that private parties can not manage biodiversity or that they should have *no* rights of any kind upon it. On the contrary, it is possible and desirable that private ownership, authorised by competent public authorities, can be extended—including rights which through buying and selling for example, allow the disposal of biodiversity much as other public commodities such as minerals. Nevertheless, the presence of State criteria is an assurance that parameters established by public order are followed, so that biodiversity does not become simply one more market item, subject to the laws of supply and demand.

It is worth noting what was expressed by Gonzalez Salazar, a congressman who helped to formulate the law, regarding Articles 3 and 4 of the law project: "I would like to contribute to this topic by saying that, since the approval of the existing Constitutional Policy, our constituents foresaw the application of property rights to public use for the Nation as being attributed exclusively to the Legislative Assembly. This declaration has its specific background in Article 89 of the Constitutional Policy, which establishes [that] the goal of the Republic is to preserve its natural wealth or beauty... . . .If we aren't clear that wild flora and fauna are the fundamental base—precisely the base of our environment—then we cannot understand the extent of this legislation ..."

Gonzalez added a series of important observations:

- there is no expropriation or limitations on property; simply, it is a matter of applying jurisprudence to public commodities;
- not all wild flora and fauna are considered, since the law itself excludes a part of this in Article 2; and
- that the wording of Article 3, declaring flora and fauna to be resources which form a part of the national wealth, be kept as is.

The considerations to which Gonzalez referred, while accurate, do not fully reaffirm what we wish to suggest here: that the determination of property rights of the Nation are expressed as Constitutional norms - the same norms that consider biodiversity as being under the public domain. Because it is in private hands, legal and constitutional considerations must affect the rules and principles governing biodiversity. However, the notion of biodiversity as a property in the public domain is in perfect accord with the considerations that the **Constitutional Court** took in sentence number 447-91 on 21 February 1991.

Thus, it is not a question of limitations to private property, but rather a consideration of biodiversity as a property in the public domain. Examples of this type of conclusion about our natural resources are found in many areas, such as mines, water, etc.

Line number 796-91 of this jurisdictional organ establishes criteria which indicate a constitutional limitation; that is, do not allow expropriation without fair indemnisation.

This should occur when there is a generalised effect (not an isolated case) and the amount of sacrifice is not especially serious. These concepts have been developed by taking into consideration the specific situation, and also the avoidance of production loss or of the market value of the property in question.

This conclusion can be reinforced by a few other reflections. In 1989 a Commission was created by decree made up primarily of members of public institutions, in order to encourage the creation of a National Institute for Biodiversity which would function as a public entity, co-ordinating sectors that work with biological diversity, in order to consolidate efforts and improve biodiversity protection. The decree's primary goal was to give regulation of biodiversity to an organisation that would represent all interests, and at the same time be responsible for the concerns of the public. In its original form, what was recognised was the need to give "control" over public properties to such an organisation. The decree, in mentioning the goals and objectives of the organisation, did not refer to any activity by a unit for private rights, nor to commercialisation of biodiversity—topics which were not being discussed in Costa Rica at that time. The fundamental discussion centred around the consolidation of protected areas and sought institutional co-ordination, of resources and efforts.

The Institute in question was never created. Rather, the Instituto Nacional de Biodiversidad (INBio) was set up, with the same name, but as a private, non-profit association that operates in accordance with principles required by these private entities (Article 1 of the Law of Associations). It is interesting here to cite the resolution of the Superior Tribunal which, in regard to a presentation against registering a commercial name for this non-governmental organisation (NGO), affirms that "the proposal of a commercial name seeks for protection against the eventuality of illegal [unfair] competition which is particular to this operation (commercial and industrial), and the lucrative activity which is involved." But the case in question has a very particular quality in that INBio is neither a commercial nor an industrial enterprise; on the contrary, it is an association whose basis for existence cannot be profitable nor lucrative. In fact, it is expressly prohibited for associations to use terms which suggest that they have different aims than that proposed in the Law of Associations.

INBio has signed a contract with Merck & Co—the exact text of which is not known—by which the trans-national firm is guaranteed access to specific biological resources of Costa Rica, including that in some National Parks. The benefits of this contract (US\$ 1,135,000 in up-front payments, a percentage of the earnings from potential products, technology transfer, training, etc.) can be regarded as good or can be criticised. One must nevertheless recognise that INBio is a private, non-profit organisation that undertakes projects related to the environment in Costa Rica.

The Law for Conservation of Wildlife, while not recognising flora as a public resource in Article 8, mentions it in Article 4 as part of the National Patrimony. The Article grants the right to extend concessions to private parties to MIRENEM. It is well known that the legal structure for concessions is applied to property in the public domain or services of a public nature, otherwise it would be a matter simply of authorisations.

Hence, Article 50, in spite of mentioning the figure of the authorisation, uses this term in a non-technical way. Thus, in spite all of the language within the text of the legislation, major differences in treatment of flora and wildlife are not found. However, the notion of "public interest" that categorises wild flowers within the wildlife law eliminates the characterisation of wild flora as property of the Nation. The simple classification as "public interest" implies a recognition that an activity transcends the private sphere and is of "collective interests". In other words, the State considers it convenient for society and the common good that such activity is carried out in accordance with the declaration of its public interest. This category is given to events such as academic, cultural, sports, and musical events and can be attributed to activities

related to biodiversity, but never to biodiversity itself, which is a property of the Nation and is submitted to a special regime of constitutional protection.

Biodiversity and International Treaties

Undoubtedly, the violation of Article 8 of the Law affects the Magna Carta. The transgressions mentioned also affect international treaties which have been duly ratified by Costa Rica, that set out constitutional parameters in the tone established in Article 2(b) and Article 73(d) of the Constitutional Judicial Law. As a result of contradicting the depositions of the treaties referred to previously, the constitutional Policy is compromised.

Article 1 of the Defence of Archaeological and Artistic Patrimony Convention of the American States (Law No. 6360 of 20 November of 1975) establishes among its objectives: "... the protection and vigilance of the property which makes up the cultural patrimony of the American States prohibiting illicit exportation and importation of their property."

Article 2 enumerates these cultural goods as "Monuments, objects, fragments of building, parts and materials pertaining to American cultures... such as human remains, and similarly, fauna and flora."

Article 5 determines the pertinence of the property mentioned in Article 2 to the Cultural Patrimony, as does the Convention for Protection of Flora, Fauna and Natural Scenic Beauty of the American States (Law No. 3763 of 19 October, 1966). It obliges its signatories to adequately protect the *flora and fauna* in protected areas, as well as outside of them (Articles 1, 3[f] and 9).

The third of the norms is especially relevant as it refers to its effects: "The contracting governments agree that, in national parks, no alterations be made unless by action of a competent legislative authority. The natural wealth existing in them will not be exploited for commercial ends." This norm, together with Article 12 of the Law of Creation of the National Parks, was considered by Pronouncement of the Procurer not to be legally sustainable in drawing up contracts between fiscal or judicial authorities and the National Parks Service for extracting and selling biodiversity.

The legislation referred to must be complemented with some depositions of the National Parks Formation Law (No. 6084 of 17 August 1977). Article 12 of this law notes, "Concession of any type must not be extended for exploitation of products from the National Parks, by permits to establish installations other than the National Parks Service." Article 8 equally prohibits the cutting of trees and extraction of plants or any other type of forest products; hunting or capturing wild animals, collecting or extracting any of their products; gathering or removing rocks, minerals, fossils or any other geologic product; and carrying out any type of commercial activity, agricultural or industrial. Regulations such as those cited are reproduced in the text of the laws or decrees that create National Parks. Thus, in some judicial depositions protected areas are created.

While the deposition of the International Convention might be considered severe and unrealistic, it is in fact now fully in force.

The declarations of Cultural Patrimony of the fauna and flora, like the obligations imposed by the Articles cited in international Conventions, provide an assurance of judicial regulation that protects the flora and fauna and impedes the commercialisation of these protected items, carrying the regulations out indiscriminately and without considering criteria or motions from the public. The only way of achieving the objectives cited by the treaties is to recognise biodiversity as being "goods of the public domain" or the Nation's property.

Conclusions

The review showed that the biological diversity of Costa Rica is defined in somewhat different ways in different laws and conventions. In my opinion, Costa Rica's biological diversity is the property of the public domain to which all existing depositions should be applied. These should equally apply to wild plants as well as animals, for which purpose I feel that the declared "public interest" expressed by the law for wild flora and fauna is unconstitutional. However, the treatment that this law gives to flora could include wild fauna, which is declared to be in the public domain. This does not mean that fauna or flora are "untouchable" by private concerns; these interests may use the flora or fauna within the regulation of the State, following constitutional and legal requirements. We could find ourselves with situations—although with some variations—such as those presented with the use and advantages of water that the National Electricity Service extends, or with the concessions that the Bureau of Geology and Mines gives to private interests, for example for extraction of raw materials. As indicated before, biodiversity is the property of the Nation, and therefore is in the public domain. It is still being debated whether, if this is the case, the State is simply an administrator of it in the name of the people. The law specifically excludes application to forestry resources, and discussion centres on whether the same applies implicitly to micro-organisms, fungi and bacteria.

In our case, all of the range of "permits" and of "authorisations" that are referred to by the Wildlife Law would constitute the system or mechanism by which private interests can utilise biodiversity. This conclusion, provided the use of the material can be conducted in a sustainable way, would permit the State to control biodiversity without it entering into the political process by making biodiversity become an element of market forces.

THE LEGISLATIVE ASSEMBLY OF THE REPUBLIC OF COSTA RICA**DECREES:****LAW OF CONSERVATION OF WILD LIFE**

ARTICLE 1.- The purpose of this Law is to establish regulations on wild life. Wild life consists on continental and island fauna that lives in natural, temporary or permanent, conditions within the national territory, and the flora that lives in natural conditions in the country. These can only be the object of particular and commercial appropriation through the dispositions contained in public treaties, in international conventions, in this Law and in its By-Laws.

ARTICLE 3.- The wild fauna constituting a renewable natural resource and which forms part of the national patrimony, is declared of public dominion. Also, the wild flora, the conservation, research, and development of genetic resources, species, races, and wild botanical and zoological varieties that constitute genetic reserves, as well as all the wild species and varieties that have entered the country and have suffered genetic modifications in their process of adaptation to the different ecosystems, are also declared of public interest.

ARTICLE 4.- The production, handling, extraction, commercialization, industrialization, and use of genetic material of wild flora and fauna, are declared of public interest and national patrimony.

To the Ministry of Natural Resources, Energy, and Mines corresponds the exercise of the activities indicated in the above paragraph; also, it is hereby authorized to grant concessions to private persons, in the terms and conditions that favor the national interest by means of public bid and according to the dispositions of this Law and its By-Laws.

ARTICLE 5.- Wild fauna in captivity and their "sustained" reproduction, as well as the flora kept in nurseries or its products does not eliminate its wild condition.

ARTICLE 17.- The Ministry of Natural Resources, Energy, and Mines is hereby authorized to grant contracts, rights of use, licenses, concessions, or any other juridical figure legally established for the conservation and the sustainable use of wild life. Also, it is hereby empowered to coordinate actions with centralized or decentralized entities that execute agricultural programs for the conservation of soils, waters, and forests, in order to manage the "sustainable" exploitation of wild life.

In the establishment and development of national wild life refuges, its inhabitants will participate in order to propitiate the community's integral development and assure the protection of ecosystems. Also, to this effect, there should exist coordination with community development associations, as well as with any other public or private organization in the area.

SYMPOSIUM ON BIODIVERSITY, BIOTECHNOLOGY AND
SUSTAINABLE DEVELOPMENT

LEGAL ISSUES: CONTRACTS, INTELLECTUAL AND OTHER PROPERTY RIGHTS

Msc. Carlos Manuel Rodriguez Echandi
INBio's Legal Counsel.

INBio, a Costa Rican NGO, is committed to insuring the survival of the protected areas of Costa Rica by finding non-destructive uses of the natural wildlands. The biodiversity prospecting at INBio has the express goal of generating income from the protected areas so as to contribute to management costs and to Costa Rica's intellectual capital and financial GNP.

INBio's activities represent first steps toward demonstrating that biodiversity resources can be made available to the commercial community without destroying the living capital. Yet, biodiversity prospecting to support conservation and further domestic economic and technological development won't succeed without close collaboration between the INBio-like institutions, the government and the multiple owner, custodians and caretakers of the wildland resources.

From INBio's perspective, the contractual challenge in biodiversity prospecting is not so much in information management because it resembles other kinds of information in the marketplace. Rather, it is making sure that the intellectual and financial net income get returned to the conservation of protected areas. INBio's goal is not to replace other industries with biodiversity prospecting but rather to help develop the information base that supports them.

Four types of collaboration are particularly vital.

First-. A national regulatory framework for biodiversity prospecting is needed to insure that protected areas can and do become full economic and intellectual partners in the commercial development of wildland biodiversity.

Second-. Infrastructure and technology must be

developed. As an intermediary between the protected areas and society, INBio integrates classical conservation, science, technology and social goals.

Third-. Formal contractual relationships among biodiversity's sources, intermediaries and final users should govern the entire bioprospecting process, from sampling and processing to the arrival of final products on the marketplace.

Fourth-. Biodiversity prospecting should attempt to move more research and development into the source country so as to contribute to the GNP.

Based on such steps INBio's conditions on all contractual agreements with commercial corporations and research institutes are the following:

1- Direct payments in cash and barter to enable INBio to develop and conduct the sampling, screening and partial characterization processes and to train and finance local scientists .

Direct compensation to tropical nations for the real costs of samples can help finance conservation programs long before chemical prospecting can begin to pay returns through royalties.

2-Payment of a significant percentage of INBio's initial project budget up to 10% and of royalties up to 50% as a direct contribution to the cost of maintaining the National Parks System.

These percentage-based payments contribute directly to meeting the management costs of conservation protected areas. INBio's current thinking is that biodiversity prospecting contribution is best channeled through the government rather than through ONG's .

3- A significant fair royalty paid on net sales to industry from the commercialization of the biodiversity materials.

The willingness of commercial firms to pay fair royalties depends on the recognition that biodiversity samples are not merely leaves from the bush, but rather are products that the supplier has systematically maintained and characterized at considerable cost.

4-Help in gradually moving drug research and development to the source country.

Biodiversity use is just one of many industrial activities in which developing countries have a chance to compete seriously, especially because they are sitting on a rich resource.

5-Minimal exclusivity.

Most of the time commercial partners want to be the sole recipient of the samples or to deny its competitors the opportunity to research on the same specimens. Such exclusivity may pose problems for Costa Rica, but without guarantee of some exclusivity pharmaceutical companies naturally aren't interested in signing contractual agreements.

6-Agreement on sample ownership and patent ownership.

Ownership of samples and extracts must be clearly defined, and the extract must either be destroyed after use or remain subject to the INBio royalty. Patents represent such an administrative headache and entail such high legal costs that INBio would much rather have a solid commercial contract guaranteeing a royalty than own the patent outright. Also in Costa Rica patenting a product produced by a living organism is legally impossible.

7-The use of chemical synthesis to avoid continuous extraction of biotic material from wildlands and to keep commercial "sourcing" in-country.

Researchers can normally make do with amounts of material that are small enough to be obtained without significantly altering the ecology of the protected areas. However few wildlands will be able to provide commercial quantities of novel chemicals found through biodiversity prospecting. INBio encourages commercial user to consider Costa Rica as their first choice for agricultural production of raw material or, alternatively to start up chemical synthesizing industries here.

8-Protective legal mechanisms.

INBio's legal agreements with commercial corporations and research institutes are generated in-house with pro bono legal counsel from local environmental lawyers and U.S. law firms specializing in patent rights and intellectual property. Since all samples are taken from the protected areas all sampling is done under the supervision from the Costa Rican government through a formal collaboration agreement.

From the industry's perspective the ideal collector requires:

- qualified scientists and access to taxonomic expertise to properly identify samples.
- sound management and administration.
- stable political and economic conditions in the collector's country.
- assurance that the collectors institution will continue to function at least for the term of the contract.

From INBio's experience both collectors and companies can achieve their objectives through agreements that can :

- Offer source countries advance payments, royalties, rights to supply future raw materials, research exchanges and funding, acces to markets and technology, and direct payments to conservation.
- Channel benefits to conservation and local peoples that contributes to research efforts without requiring new definitions of property rights or special legislation.
- Ensure economic returns for the work involved in collecting samples as well as for the collected materials itself.

Calculation of Royalties.

The payment of royalties on the sale of products derived from compounds discovered in plants and animals is a new commercial practice, so few direct precedents exist to guide the calculation of royalty rates. In a new field of business like biodiversity propecting, there is no pool of transactions, no

clearly defined market, and thus no single market value or established royalty rate.

Intellectual Property Rights.

Intellectual property laws, typically viewed only as engines of industrial and cultural progress, have recently received attention as tools for achieving the broader goals of conserving biodiversity while promoting sustainable development.

The greater the range of intellectual property protection available in a country, the more choices the inventor has to protect the fruits of research, development and marketing. Developing nations seeking to promote biodiversity prospecting, domestic innovation, and technology acquisition should have a modern intellectual property legislation that includes regulation on trade secret, patent protection in a supportive economic and political climate. This new legislation should be tailored to balance rights between the exclusive private domain and the public domain.

For now there is no international agreement on the optional interplay between biodiversity, biotechnology transfer and intellectual property rights. Until a consensus or compromise is reached, unresolved disputes will impede efforts to rely on intellectual property rights as a tool for conserving biodiversity. The Convention on Biological Diversity ensures that the role of intellectual property in the sustainable development of genetic resources will continue to receive attention. Future interpretations of the Convention and domestic laws should help promote mechanisms that make habitat conservation worthwhile and ensure that those who conserve the wildlands are properly rewarded for their efforts.

Costa Rica's Legislation.

Under Costa Rica's legislation any entity that wants to collect or manage biodiversity samples from the protected areas for commercial or other uses must sign a concession agreement with MIRENEM. This legislation declares all wild animals, including invertebrates, to be 'national patrimony' of public domain, regardless of whose property they inhabit. Plants are considered

as private property of public interest. Thus, even the private landowner needs a concessionary agreement from MIRENEM to collect or manipulate plants. The laws states firmly that "the terms and conditions of the concessions must favor national interests".

How this legislation will avoid running afoul of the Costa Rican constitution, which allows landowners to "do or undo" in their own land, is an important legal question. The recently created constitutional court has ruled that the constitution principle of property is not absolute, and that the law can impose limitations based on "public interest" or "ecological interests". Still there's a atmosphere of legal uncertainty around the use of biodiversity that has put a big burden on INBio and similar institutions in Costa Rica.

Contracts between companies and collectors reflect well-defined relationships based on an agreement to exchange and screen samples for the commercialization of natural products. Alone, they cannot produce new leads for drug discovery, guarantee scientific research and training, provide incentives for conservation, increase the use of traditional knowledge, ensure equitable distribution of benefits to all parties. Although contracts can significantly contribute to all of these goals, many will be achieved only in conjunction with fundamental changes in international and national law and policy.

As an increasing number of companies become involved in natural products research, the demand for samples is increasing, and with it the prospects for unrestrained and inequitable collection of biological samples. Not only can contracts between collectors and companies guarantee firms a well-identified, reliable supply of samples; they can also provide a framework for ensuring that a significant immediate and long-term benefits accrue to collectors and countries of collection.

To commercialize biodiversity successfully, Costa Rica must stay on the cutting edge of new commercial development as it has in the development of its National Parks. Indeed INBio must aggressively seek users and point out new potential uses, as well as help foster a political and legislative climate in Costa Rica that is hospitable to innovation. Of course, the commercialization of wildland biodiversity is a two-edged sword. While it is a

good way of getting tropical wildlands to pay for themselves and to get the general public on their side, it also antagonizes free-wheeling bioprospecting competitors who naturally want to continue to reap personal profits as well as those who disapprove the marriage of commerce and conservation. This unavoidable antagonism must be handled at the negotiating table.

**COOPERATION AGREEMENT BETWEEN THE MINISTRY OF NATURAL RESOURCES,
ENERGY, AND MINES AND THE NATIONAL BIODIVERSITY INSTITUTE
ASSOCIATION**

We, René Castro Salazar, of legal age, married once, Civil Engineer, resident of Sabana Norte, bearer of I.D. card number one-five hundred and eighteen-one hundred and eighty one, in my condition of Minister of Natural Resources, Energy, and Mines, according to Designation Decree Nº 23308-P, published in La Gaceta Nº 88 of May 9, nineteen hundred and ninety four, hereinafter referred to as THE MINISTRY, and Rodrigo Gámez Lobo, of legal age, married once, Doctor in Virology, resident of Heredia, bearer of I.D. Card number six-zero forty six-three hundred and sixty, in my condition of President of the National Biodiversity Institute Association, with domicile in Santo Domingo, Heredia, corporate I.D. number 3-002-103261-12, recorded in the Public Registry, Associations' Section, under file Nº 3306, hereinafter referred to as INBio, have agree in entering into this Cooperation Agreement, which will be ruled by the background and normative dispositions detailed hereinafter:

BACKGROUND

FIRST: That the Law of Conversion of the Ministry of Industry, Energy, and Mines into the Ministry of Natural Resources, Energy, and Mines, 7152 of June 21, 1990, published in La Gaceta Nº 117, established in its Article Second, clause e) as function of THE MINISTRY: "To promote the scientific and technological research related with the subject matters of its competence, in coordination with the Ministry of Science and Technology". Also indicating in its clause j) the following: "Promote and develop environmental formation programs at all educational levels and towards the public in general. Carry out inventories of the natural resources with which the country counts."

SECOND: That in accordance with the terms of Law Nº 7174 (Modification to the Forestry Law, dated June 28, 1990, published in La Gaceta Nº 133 of July 16th of that same year, it was established in its Second Title, Chapter First, Article 35, the referred to "Forestry State Patrimony", which is constituted by Forest Reserves, National Parks, Wild Life Refugees, Protecting Zones, and Biological Reserves, which are destined for protection of its natural resources, in function of sustainable use, as for the "conservation, study, and research of wild life and of the ecosystems existing therein".

THIRD: That Law Nº 7317, Law of Conservation of Wild Life, dated December 7, 1992, establishes also the legitimacy of Costa Ricans or foreigners to exercise scientific or cultural collection activities, such as the carrying out of research with regards to wild flora and fauna within the national territory; indicating the following in its Article 36:

"Costa Ricans and foreigners are authorized to practice scientific or cultural collection of animals and plants, of its products or by-products and to carry out research, provided they do not contravene this Law or its By-Laws."

FOURTH: That Executive Decree Nº 22545-MIRENEM, published in La Gaceta Nº 195 of October 13, 1993, By-Laws to the Law of Conservation of Wild Life, establishes the following to that respect:

Article 61.- "The scientific or cultural collection of wild fauna and flora can be carried out in the national parks and biological reserves, since they are public dominion goods, after obtaining the "O.K." from the National Parks' Service, which will be the entity directly responsible for the vigilance and supervision of this collection, without impairment of the faculties that the Law and these By-Laws grant the General Wild Life Bureau".

FIFTH: That Law Nº 7169, of August 1, 1990, Law for the Promotion of Scientific and Technological Development, established as its general objective, the facilitating of the scientific and technological innovation, with the purpose of leading to a greater promotion of the integral sustainable development, in benefit of future generations, declaring the following in its article 8:

Article 8.- "Non-profit scientific and technological activities, carried out by entities that form part of the National Science and Technology System, are declared of public interest."

According to articles 1, 5, 7, and 25 of Law 7169, Law for the Promotion of Scientific and Technological Development, and 2, 5, and 17 of the By-Laws of the Scientific and Technological Registry, INBio is recorded as a national scientific Institution, and forms part of the National Science and Technology System.

SIXTH: INBio as National Scientific Institution, duly registered as such (Scientific Registry and National Flora and Fauna Registry), is duly credited to maintain collections of biological specimens according to articles 19, 24, and 46 of the Law of Conservation of Wild Life, and to article 56 of the By-Laws to the Law of Conservation of Wild Life.

SEVENTH: That by means of Executive Decree Nº 12329-A, the By-Laws for Research for the Service of National Parks, in La Gaceta Nº 46 of March 6, 1981, was published, authorizing the extraction and scientific collection of biological samples; the destination of which should be the National Parks' Service, or else scientific or educational institutions that can give an ulterior appropriate use.

EIGHTH: INBio is a non-profit organization, the objective of which is to contribute with the conservation to perpetuity of the biodiversity existing in the national territory, promoting its integration to Society's intellectual and economic values, by generating and disseminating knowledge on identity, geographical distribution, and uses of species of plants, animals, and micro-organisms existing therein.

NINTH: That one of the fundamental objectives for the protection and conservation of wild areas is scientific research; which leads to improve knowledge and implement conservation of the biological diversity existing in those areas, such as the creation of benefits for the Costa Rican society. To that effect, the convention for the protection of flora, fauna, and natural

scenic beauties of American countries, ratified by Law 3773 of October 19, 1976, authorizes in its article 3, the collection of flora specimens in the National Parks when made for duly authorized scientific research, aspect equally ruled by the recent Convention on Biological Biodiversity.

TENTH: That Law Nº 7416, published in La Gaceta Nº 143 of July 28, 1994, ratifies the Convention on Biological Biodiversity signed by the Government of Costa Rica during the "Earth Summit" of June 5, 1992, establishing the following in its article first:

"This Convention's objectives, which should be pursued in accordance with pertinent dispositions, are the conservation of biological diversity, the sustainable use of its components, and the just and equitable participation in the benefits derived from the use of genetic resources, by means, amongst other things, of an adequate access to those resources and an appropriate transference of pertinent technologies, taking into account all the rights over those resources and to those technologies, as well as by means of an appropriate financing."

ELEVENTH: That INBio and the MINISTRY have previously developed several research programs, decision which was adopted in function of the knowledge, technical experience, and whatever financing this non-profit scientific association has available.

TWELFTH: That it is necessary to re-adequate and increase the Cooperation Agreement subscribed between MIRENEM and INBio on May 11, nineteen hundred and ninety two, so that its dispositions may adjust themselves to the factual reality of scientific and educational research on this subject, having to adjust in everything related to the legal and regulatory dispositions quoted.

THIRTEENTH: That there has been a close and satisfactory coordination between the MINISTRY and INBio in as far as cooperation and research, being the latter an instrument of valuable collaboration for the MINISTRY, since this Institution does not have the appropriate technical elements required to develop the object of this agreement.

FOURTEENTH: That by means of agreement of its Board of Directors in meeting Nº 38 of September 16, 1994, Article 2, INBio authorized its President, Doctor Rodrigo Gámez Lobo, to subscribe this Cooperation Agreement.

CLAUSES

FIRST: INBio will continue carrying out together with THE MINISTRY, the national biodiversity inventory, in the system of protected areas, by executing research projects, in accordance with the procedures and regulations stipulated to that effect, by the legislation in force.

INBio, as duly credited scientific institution (Article 24, Law of Conservation of Wild Life and Articles Nos. 7 and 8 of the Law for the Promotion of Scientific and Technological Development), will maintain a collection of all specimens collected, duly registered and ordered to permit an easy access to the public that needs to study them, or to officials who require their study or review: this in compliance with Article Nº 6 of the By-Laws for the Research of National Parks' Service (Executive Decree Nº 12329-A) and of the Law of the Conservation of Wild Life.

The biological samples collected for the Inventory cannot be totally nor partially commercialized, and contempt to this respect will imply the immediate rescission of this cooperation agreement, as well as the application of the penal sanctions in force in the Law of Conservation of Wild Life.

SECOND: In order to carry out the work of scientific research, THE MINISTRY will grant INBio's technicians and scientists, official specific identification.

Both institutions will also provide the necessary installations and equipment to manage compliance with the objectives of this cooperation agreement; there being availability from INBio of donating THE MINISTRY the required equipment and materials to comply with the purposes indicated, which should be formally inventoried within the National Patrimony.

THIRD: All research projects should count with the corresponding research permits, issued by the National Parks, Forestry, and Wild Life Bureaus, in accordance with their corresponding competence.

FOURTH: The activity of collection of specimens on the part of INBio will be carried out in such a way that it does not cause any damage or alteration that may imply or constitute a threat to the biodiversity of the site from where they are extracted; having to comply at all times with the existing legislation and regulations, such as the correct application of the technical criteria issued to that respect by THE MINISTRY's authorities.

FIFTH: INBio promises to provide THE MINISTRY and its General Bureaus the technical counselling they may require for the study and evaluation of projects or other activities related with the conservation of biodiversity; it will also impart training workshops or courses, in order to up-date and inform of the latest methods and operational systems motivated by INBio in its projects.

The training of MINISTRY officials is a fundamental part of this cooperation agreement, based on mutual agreement programs.

SIXTH: THE MINISTRY and INBio, through their credited officials, should carry out due control in order to determine that samples extracted strictly obey those previously authorized by the corresponding research permits. They will also see that samples are at all times manipulated correctly.

SEVENTH: INBio will present an annual list of persons credited by that Institution to carry out research projects within the wild areas managed by THE MINISTRY. These officials will enter wearing their corresponding uniforms, or with visible identifications.

EIGHTH: Closely following the dispositions of the Legislation in force, THE MINISTRY will grant INBio permission to collect samples of different vegetable, insect, or other biological species; so these may be used in scientific research with a biodiversity prospection.

INBio will also indicate the site and amount of samples to be collected, according to the demands of their corresponding research permits. These samples cannot be wholly nor partially commercialized, being its non-compliance subject to the sanctions stipulated in clause First of this juridical instrument.

Also, for the collection of these samples subjected to biodiversity prospection, THE MINISTRY should be informed of the techniques and procedures to be followed for their due handling, so that this collection will not present any tangible alteration whatsoever of the ecosystem providing them.

NINTH: INBio authorizes supervision and auditing on the part of THE MINISTRY, or of whatever officials the latter designates, so that the dispositions of these Cooperation Agreement be verified. It also promises to render in detail the reports that to that effect THE MINISTRY determines to request.

TENTH: In those cases where scientific research is published or disseminated in any means of communication, INBio should credit the origin of the Cooperation Agreement INBio-MIRENEM.

ELEVENTH: In all research projects on Biodiversity Prospection, INBio should include a heading equivalent to at least ten percent of its total budget, as contribution to the handling and conservation of the conservation areas.

In those cases where it is impossible to contribute with this heading, THE MINISTRY can authorize the research when its importance is of public interest.

TWELFTH: When INBio receives as result of the application of its knowledge, in function of the scientific research carried out in the field of Biodiversity Prospection, economic or material benefits, it promises to transfer to THE MINISTRY, fifty percent of the benefits corresponding to it, which will be exclusively invested for the handling and conservation of the wild areas managed by THE MINISTRY.

THIRTEENTH: The Cooperation Agreement subscribed between the parties on May 11, 1992, is hereby annulled. This Agreement rules beginning on the date it is signed, having a five-year life, and will be automatically renewed for periods having the same dura-

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tion. In case any of the parties wishes to rescind or modify it, it should notify the other party in writing at least six months in advance.

In witness whereof, we sign in the city of San José, on the seventh day of the month of October, nineteen hundred and ninety four.

(signature)
Eng. René Castro Salazar
Minister, MIRENEM

(signature)
Dr. Rodrigo Gámez Lobo
General Director, INBio

SEAL

PERMITS FOR COLLECTING BIOLOGICAL MATERIAL IN COSTA RICAN PROTECTED AREAS

In order to gain access to biological resources found within the borders of publicly protected lands in Costa Rica, all researchers (including INBio) must complete a number of steps and fill out the appropriate forms. Authorization must be granted by both the General Wildlife Bureau and the National Park Service, although it is ultimately the General Wildlife Bureau that has the final authority to grant permission for collection; the other entities approve the research project in the stages preceding final permission.

At present, any researcher wishing to collect biological materials in a government protected area (such as a national park or reserve) must first obtain authorization from the specific Conservation Area where the research will actually be carried out. This approval is obtained by completing the "Permission for Investigation and Research"(1)¹ form.

With permission obtained from the Conservation Area, the researcher must fill out the "Research Activity Registration Form"(2) (from the General Bureau of Wildlife) and present it at the Bureau together with the following requirements:

- The institution employing the researcher must be certified in the National Registry of Flora and Fauna;
- Approval from the Conservation Area where research will be conducted must be included;
- Request for research must be authenticated by the Costa Rican Consular Service;
- A copy of the project proposal in Spanish must be submitted;
- The receipt(3) verifying the payment of a *canon* (¢350 for national researchers, \$US30.00 for foreign researchers) to a State bank must be included;

Once these various documents have been submitted together with the Research Activity Registration Form, the research project will either be accepted or rejected by the General Wildlife Bureau. If approved, the researcher will be authorized to collect biological samples from protected areas under the "Resolution"(4) granted by the General Wildlife Bureau. With the Wildlife Bureau resolution in hand, it then becomes the Conservation Area's (site of investigation) responsibility to provide lodging and other necessities to researchers.

Under the current plan to decentralize government authority of the Costa Rican Conservation Areas, the steps outlined here are presently being redrafted in order to simplify the process of obtaining permission and place it in the hands of the Conservation Areas themselves.

¹ Four permits are introduced here and are attached in the order they have been mentioned, according the number (1-4) following their titles.

MINISTERIO DE RECURSOS NATURALES, ENERRGIA Y MINAS
SERVICIO DE PARQUES NACIONALES

PERMISSION FOR INVESTIGATION AND RESEARCH

The National Parks' Service of Costa Rica authorizes Mr./Mrs. _____

to conduct research on: _____

From _____ to _____ In the zones: _____

Number of individuals accompanying: _____

They are authroized to collect only _____

They will be granted the facilities corresponding to them, provided they do not interfere with the
personnel's work. These are: _____

- * THE PARTY MUST DEPOSIT _____ COLLECTION IN THE NATIONAL MUSEUM
- * REPORTS MUST BE SUBMIT ON: _____

This permission may be REVOKED at any time by the National Parks' Service, with out any
responsibility whatsoever on the part of this Bureau, if the investigator should not comply with the
declaration made in his/her request for permission date _____, or for any
unforseen reasons, or causes beyond control.

THIS PERMISSION IS CONDITIONED TO COMPLIANCE WITH DISPOSITIONS STATED IN
THE LAW FOR WILDLIFE CONSERVATION, IT BY-LAWS, AND BY THE NATIONAL
PARKS' SERVICE'S VY-LAWS REGARDING RESEARCH AND INVESTIGATION

Permissions authorized by : _____

Subdirector
Servicio Parques Nacionales

Investigation and Research Section
MIRENEM

MINISTRY OF NATURAL RESOURCES, ENERGY AND MINES
GENERAL WILDLIFE BUREAU

RESEARCH ACTIVITY REGISTRATION FORM

NAME OF RESEARCHER: _____

PASSPORT NUMBER: _____

MAILING ADDRESS: _____

FAX NUMBER: _____

NAME OF THE UNIVERSITY OR INSTITUTION WHERE YOU WORK : _____

RESEARCH PROJECT OR INVESTIGATION TO BE CARRIED OUT: _____

RESEARCH OBJECTIVE: _____

SITE WHERE RESEARCH WILL BE CARRIED OUT: _____

EXPECTED DURATION OF RESEARCH PROJECT: _____

SOURCE OF FINANCING FOR RESEARCH: _____

POSSIBLE PROJECT RESULTS: _____

I NEED TO COLLECT (include species and number of specimens) _____

ADDRESS IN COSTA RICA FOR NOTIFICATIONS: _____

OTHER REQUIREMENTS ESTABLISHED BY LAW

Authenticated certification from the corresponding authorities from the institution where the requestor is studying or working.

Request for research authenticated by a representative of the Costa Rican Consular service.

Should collecting take place in a particular farm or areas protected by the State, written permission must be obtained and submitted from whoever is legally authorized.

A copy of the research project in Spanish must be attached.

Receipt from a State bank for the ₡350 colones-canon, or U.S. \$30 equivalent for foreigners, who have been granted a scientific license.

Receipt #: _____ Bank _____

RESOLUTION N° 245.94.DER

The MINISTRY OF NATURAL RESOURCES, ENERGY AND MINES, General Bureau of Wildlife, Resource Evaluation Department, at nine o'clock on October third, nineteen hundred and ninety-four.

WHEREAS:

FIRST: That on date, Mr./Mrs./Dr. _____

residing in _____, officials of _____,
_____ project # _____, project of _____ research and _____
of:

- material for collection

_____ g _____ of each species

- material for collection

_____ # _____ of individuals of each species

IN CONSIDERATION OF

FIRST: That based on articles one and three, of the Wildlife Conservation Law, Law number seven thousand three hundred and seventeen of December seventh, nineteen hundred and ninety two, declares that the wildlife is conformed by the continental and insular fauna living in natural conditions, which lives in natural conditions in the country; and that they can only be the object of particular and commercial appropriation by means of the dispositions contained in the public treaties, in the international conventions, and in this Law and its by-laws, articles 3 and 36 to 50.

SECOND: That according to Law N° 7317, Wildlife Conservation Law, in its article 6 it establishes that the General Wildlife Bureau is the competent organization in the planning, development, and control of fauna and wildlife.

THIRD: That Mr./Mrs./Dr. _____

_____, completed the requisites for registration of investigations and scientific collections established in Law N° 7317, Wildlife Conservation Law and its By-Laws.

Therefore:

THE HEAD OF THE RESOURCE EVALUATION DEPARTMENT

RESOLVES:

FIRST: To approve the _____ to investigate of Mr./Mrs./Dr. _____

_____ all officials of the _____.

SECOND: Grant the license of scientific or cultural collection to the above-mentioned gentlemen, for the following:

- material for collection _____ § _____ of each species

- material for collection _____ # _____ of individuals of each species

THIRD: The General Wildlife Bureau reserves for itself the right to cancel this permission without any responsibility whatsoever for the State, when it proves it has non-complied with it.

FOURTH: The licensee cannot assign or in any alienate the permission, since it is non-transferable.

FIFTH: The licensee should allow officials from the General Wildlife Bureau to enter the place where the investigation and the scientific or cultural is being carried out.

SIXTH: The General Wildlife Bureau will only authorize those methods of scientific collection detailed in the By-Laws of Law N° 7317, Law of Wildlife Conservation.

SEVENTH: The licensee promises to send copy of the publications to the National Library and to the General Wildlife Bureau on the publications generated by this investigation permission.

EIGHTH: This permission is valid only for the state protected areas managed by the National Parks' Service, as established in the _____.

NINTH: This permission is in force beginning on the _____ date, up until _____ date _____.

Original signed) **Juan Ma. Rodríguez**
JUAN MA. RODRIGUEZ RAMIREZ
HEAD DEPARTMENT OF EVALUATION OF BIOLOGICAL RESOURCES

Original signed) **Lic. Antonio Darío Carazo**
OK JURIDICAL COUNSELLING

SECTION 3

TWO APPROACHES TO DIRECTED INVENTORIES

SECTION 3: TWO APPROACHES TO DIRECTED BIOPROSPECTING INVENTORIES

Introduction:

The first step in any bioprospecting program is to inventory biological and genetic resources, so that researchers may better know the materials and understand their potential. Inventories can be completely random, involving plants or insects or microbes or marine organisms, or they can be directed. Two types of directed bioprospecting inventories are ethnobotanical inventories and ecological inventories.

Ethnobotanical inventories, discussed here in a paper by Dr. Maurice Iwu, make use of the traditional knowledge of indigenous or other rural communities. Inventorying traditional knowledge may supply important clues for the development of new commercial products such as pharmaceuticals or pesticides. However, the use of traditional knowledge in this way also raises serious ethical concerns and must be approached carefully. At the very least, researchers seeking access to traditional knowledge for commercial development must pay strict attention to the need to obtain prior informed consent from the communities supplying the knowledge. Offering fair compensation in exchange for access to this knowledge is also crucial.

Ecological inventories employ collectors trained to observe ecological interactions among species. Interesting relationships between species, e.g. between plant and herbivore, predator and prey, or host and parasite, may suggest that these organisms are producing secondary metabolites with useful chemical properties. The paper presented here by Dr. Daniel Janzen discusses the importance of inventories as an important step to employing more specific ecological inventories or leads for biodiversity prospecting.¹ Janzen examines the broader implications of sampling over a wide range of biodiversity taxa as well, and how this might encourage resource conservation. The "All Taxa Biodiversity Inventory" (ATBI) for Costa Rica is also introduced here, and how such a project might generate new uses for wild biodiversity, ultimately producing new incentives for conservation.

¹ However, it is important to note that INBio's National Biodiversity Inventory is an activity completely separate from bioprospecting, and is not intended to be an ecological inventory for the purpose of natural product research and development. Rather, the National Biodiversity Inventory is a taxonomic exercise that will have a wide application, and whose *associated information* serves as a type of ecological inventory supporting potentially interesting genetic resources and the relevant information gathered for bioprospecting.

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Contents: Section 3

- African medicinal plants in the search for new drugs based on ethnobotanical leads. By Maurice M. Iwu (reprinted with permission)
- Wildland Biodiversity Management in the Tropics: Where are we now and where are we going. By Daniel H. Janzen (reprinted with permission)

Additional Reading: Section 3

- Farnsworth, N.R. & D.D. Soejarto. 1991. Global Importance of Medicinal Plants. *In* Akerele, O., Heywood V. & H. Synge, (eds.). *The Conservation of Medicinal Plants*. Cambridge: Cambridge University Press.
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WILDLAND BIODIVERSITY MANAGEMENT IN THE TROPICS: WHERE ARE WE NOW AND WHERE ARE WE GOING?

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Where are we now?

Humans have been studying wildland biodiversity as long as there have been humans. The goal was extirpating, eating, avoiding, inhaling, domesticating, controlling and predicting. And we have sought simplification and homogenization of the natural world to facilitate these activities.

The outcome is that any given tropical nation or large multinational region has today three basic kinds of land use: urban, ever more intensively managed agroscape, and ever-dwindling wildlands. The latter are generally patches of comparatively biodiverse habitats on socially or physically inaccessible sites, and or on 'poor' agricultural soils.

The urban habitat is viewed as productive even if restive. The agroscape is productive and largely pacific. And the wildlands are largely viewed as removable, conservable or conserved - that is to say, set aside by someone 'else' for strip-mining of their natural products or for social fossilization, outside of the national economy. Like cash in a shoebox under the bed, neither earning interest nor circulating.

This view of tropical wildlands is wrong, and fortunately waning in popularity. There are encouraging nuclei of voices dotted across the tropical (and extra-tropical) landscape arguing "Conservable and conserved tropical wildlands" are a category of highly productive land use. Conserved wildlands are a different kind of field, just as ecotourists are a better kind of cow, just as drug precursors are another kind of cotton, just as biodiversity literacy is another kind of rice. And in contrast to pastures, fields and paddies, all three biodiversity products, and many more, can come from the same hectare.

Such a shift in social attitude demands that a conserved

wildland be blessed with the level of planning, knowledge, investment, oversight, budget, technology, political attention, etc. that has long been characteristic of the more productive sectors of the agroscape, and also of a nation's institutions: roads and highways, hospitals, education, communication, etc. Traditional tropical conserved wildland management; "fence it and put a guard on it" - is to such a blessing as a guard at the bank's front door is to the stock market, Federal Reserve, free market economy, taxes and trade barriers all rolled into one.

We may anticipate a new edition of 'potential land use' maps for tropical countries. This is really what the 'thou shalt inventory thy biodiversity' component of the Biodiversity Treaty is all about. No longer will there be a soil map marked 'apt for agriculture', 'apt for forestry' and 'apt for conservation', with 'conservation' meaning 'useless' and therefore to be assigned to the national park service or its equivalent. Rather, these maps will be of what has been explicitly designated as agroscape and wildlands conserved for their biodiversity, with awareness that any hectare can be developed as either, depending on society and history rather than on soil type, rainfall, slope, and distance from a road or border war. And the overall goal will be to render both land use types maximally productive, high quality, and much valued by a nation and a region.

Up to the present, relatively non-damaging consumption from wildlands - humanity's hallmark during the first 99% of human evolution - has gradually lost out in competition with the agroscape. Today's wildlands are substantially less productive than are many kinds of agroscares. Humanity has cleared the way for its domesticates - including humans that function as urban or rural draft animals - and invested huge amounts in domestication. However, as the agroscape becomes ubiquitous across the tropics, the scarcity value of the multiple-use conserved wildland increases for society as a whole, and nations specifically. Simultaneously, as humanity's desires become more diverse and more perceptive, the value of a unit of wild biodiversity increases. Finally, as humanity's knowledge base increases in bulk and interconnectivity, the intrinsic multi-use potential of a unit

This essay appears here at the request of the editors of Vida Silvestre Neotropical. It will also appear in the symposium volume of the Inaugural Symposium of the Consortium for Systematics and Biodiversity, "Biodiversity: 1986 to the 21st Century", held at the Smithsonian Institution, November 18-19, 1993. This "double publishing" of an essay is deemed necessary to reach the very broad audience concerned with the fate of Neotropical biodiversity.

Vida Silvestre Neotropical 3:3-15
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African medicinal plants in the search for new drugs based on ethnobotanical leads

Maurice M. Iwu

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Abstract. In the African world view the natural environment is a living entity whose components are intrinsically bound to mankind. Dietary plants, spices and common herbs dominate the materia medica, in contrast with modern orthodox medicine which uses many regulated poisons. Drug development based on ethnobotanical leads has followed two paths: the classical approach of identification of single plant species with biologically active compounds and the characterization and standardization of traditional recipes for reformulation as medicines. The first approach has led to the recognition of many African plants as medicines and the isolation of several biologically active molecules; examples range from the well known physostigmine (from *Physostigma venenosum*) used for the treatment of glaucoma to the recently identified antiviral agents from *Ancistrocladus abbreviatus*. The second approach which aims at optimization of mixed remedies as formulated dosage forms is perhaps more relevant to the needs of the poor rural populations but has remained largely ignored. Drug development programmes based on ethnobotanical leads must provide for just and fair compensation for individual informants and local communities.

1994 Ethnobotany and the search for new drugs. Wiley, Chichester (Ciba Foundation Symposium 185) p 116-129

Culturally, Africa would appear to be extremely heterogenous with well over 2000 distinct tribes and as many languages and dialects; however, certain common threads run through most traditional medical systems in the continent. An example is the near total reliance on plants for sources of ingredients for the formulation of remedies. Animal parts, insects and certain clays are used in a rather limited sense. Another common feature is the strong influence of religion in the diagnosis of diseases and prescription of remedies.

The continent, with its long history of human civilization and centuries old record of the use of plants as medicine, is a rich source of leads for the development of new therapeutic agents. Indeed, many modern pharmaceuticals

and everyday herbs owe their origin to Africa. Many scientific groups are currently exploring African flora for new compounds with pharmacological activities. Such efforts have led to the isolation of several biologically active molecules that are in various stages of development as pharmaceuticals (Iwu 1993). There is therefore little doubt that a systematic ethnobotanical study of African plants is a viable approach for the development of new therapeutic agents; the unsettled questions, however, concern the methods to be followed for such studies. What criteria should be adopted to protect the cultural integrity of the host communities from being completely destroyed by the investigators? What type of drugs should be developed? Should the health needs of developed countries be the sole criterion for determining the usefulness of the medicinal plants? In a fundamental sense is it ethical to isolate the cure from the system that produced and nurtured it? Even the basic question of what constitutes a medicine has to be addressed: should we be forced to accept the reductionist Cartesian model of therapeutics as the basic framework for ethnobotanical studies?

This paper will focus on Africa and will be largely limited to our experience in the development of drugs based on ethnobotanical leads. I shall begin with a brief discussion of the fundamentals of African traditional medicine and world view, followed by an overview of drug development programmes based on the utilization of African plants. I shall conclude by giving insights into some of our current projects in ethnobotany and biodiversity prospecting, including the Salvage Ethnography Project, the KIBORD (Kates Institute of Bio-organic Research and Development) initiative and the Bioresources Development and Conservation Programme, as well as our joint projects with Shaman Pharmaceuticals Inc. and the Walter Reed Army Institute of Research. These projects differ significantly in their objectives, scope and methodology but unfortunately time will not allow a detailed discussion.

Several factors have limited the search for new drugs from African plants. Three of these have seriously undermined otherwise well conceived projects. The first is the inadequate appreciation of the relationship between indigenous African communities and the environment. There is a strong belief in the *sacrality* of the Earth, according to which, not only is the Earth considered sacred but precise rules and rituals are prescribed for the proper use of its bounties. It is therefore very difficult to separate the purely physical properties of plants from their spiritual attributes. The second limiting factor has been the near total devastation of waves of colonial rule and the enduring disruptive effect of the more aggressive and dominant European culture. For example, most of traditional medicine consists of mixtures of various herbs, whereas European drugs are mainly isolated compounds obtained from single plants. When ethnobotanical surveys are conducted in Africa, it is usually not to record the general relationship between the local communities and plants but to discover whether any of the plants contain chemicals for development as drugs for European medicine.



A third limiting factor, which is perhaps global, is the fact that the early investigations of African remedies were conducted by anthropologists who were more concerned with exotic tales of 'primitive' tribes with bizarre habits than undertaking the often dry chore of recording countless remedies in jaw-breaking languages. Even today, although the multidisciplinary nature of ethnobotany is espoused by nearly all those involved in the subject, most ethnobotanical studies are conducted not by multidisciplinary teams with qualified medical practitioners, botanists and ethnographers but by individual botanists with limited medical knowledge or worse still by pharmacists and chemists with very poor training in plant taxonomy. A study of African medicinal plants must begin with the broad consideration of the role of plants in the practice of traditional medicine. A proper ethnobotanical investigation aimed at drug development should take into account the medical system in which the plants are used.

Traditional African medicine belongs to what have been classified as *personalistic* systems in which supernatural causes ascribed to angry deities, ghosts, ancestors and witches predominate, in contrast with the *naturalistic* systems where illness is explained in impersonal, systemic terms (Bannerman et al 1983). In the African system of medicine, healing is concerned with the utilization of human energy, the environment and the cosmic balance of natural forces as tools in healing. In the African world, the natural environment is a living entity, whose components—the land, sea, atmosphere, and the faunas and floras—are intrinsically bound to humans. Plants therefore play a participatory role in healing. A healer's power is determined not by the number of efficacious herbs he knows but by the magnitude of his understanding of the natural laws and his ability to utilize them for the benefit of his patient and the whole community. Treatment therefore is not limited to the sterile use of different leaves, roots, fruits, barks, grasses and various objects like minerals, dead insects, bones, feathers, shells, eggs, powders and the smoke from different burning objects for the cure and prevention of diseases. If a sick person is given a leaf infusion to drink, he or she drinks it believing not only in the organic properties of the plant but also in the magical or spiritual force imbibed by Nature in all living things and in the role of his or her ancestors, spirits and gods in the healing processes (Iwu 1990). The African healer, therefore, could play one or more of the following roles: medicineman, diviner, adjudicator, protector against natural and supernatural forces, and enhancer of success.

Another major characteristic of the African materia medica is the dominant use of edible plants as medicines, in contrast with the modern orthodox medicine in which drugs are essentially poisons that, if taken in regulated doses, may be useful in treating diseases. Everyday culinary plants when processed in a prescribed manner, often different from their nutritional use, provide the traditional healer with most of his remedies.

Medicinal plants and drug development in Africa

Medicinal plants are used in five main ways in Africa: 1) as ingredients for the preparation of traditional remedies; 2) as herbs in medicinal soups and teas; 3) for the preparation of pharmaceutical galenicals; 4) as phytomedicines prepared in standardized forms but retaining essential features of their traditional use; and 5) as sources of biologically active compounds for the development of pharmaceutical dosage forms. In the first type, the plants are usually collected fresh and when needed, except for those that require prior drying or are available only in certain seasons or distant locations, in which case they are collected and stored until needed. This method accounts for the bulk of medicinal plant use in the continent. Herbal teas and medicinal soups account for the second major type of plant use. Only a few standardized phytomedicines are manufactured locally in Africa. Pilot projects to manufacture local plant medicines as standardized drugs have been initiated in Rwanda, Botswana, Egypt, Mali, Nigeria, Kenya and many other countries. Local investigation of medicinal plants for the isolation of pure compounds has been limited to phytochemical analysis of plants rather than a systematic and purposeful programme of drug development.

The Organization of African Unity's Science & Technology Research Council has pioneered a series of projects aimed at the standardization of plants used in traditional African medicine and the evaluation of plants as sources of biologically active compounds. The study has resulted in the publication of an African pharmacopoeia, a two volume compendium of plant medicine from the continent and methods for their standardization (Organization of African Unity 1986). In 1978, the World Health Organization initiated a medicinal plants evaluation programme. Many African plants were included in the more than 20 000 plant species identified in that study. The Nigerian Society of Pharmacognosy reviewed the study of medicinal plants in Nigeria and selected 12 plants for further development (Sofowora 1986).

One of the most active natural products networks, NAPRECA (Natural Products Research Networks for Eastern and Central Africa), has been coordinating studies on medicinal plants of Eastern and Central Africa. NAPRECA, which held its 5th Symposium in September 1993, publishes a newsletter on various aspects of medicinal plant study for its members.

Many of the transnational pharmaceutical companies have in-house drug development programmes that include several plants collected from Africa. Over a dozen European, Japanese and US companies have obtained their raw source materials from Africa. In nearly all cases, these companies treat the host countries where the plants are collected as global warehouses to be exploited at will and abandoned when the supplies are depleted.

Salvage Ethnography Project

The Institute of African Studies, the Faculty of Arts and the Department of Pharmacognosy, all of the University of Nigeria, Nsukka, in 1982 initiated a

'Salvage Ethnography Project' which was aimed at providing documentation on the *Nka-na-Nzere* of the Igbo people of south-eastern Nigeria. *Nka-na-Nzere* does not have an equivalent phrase in English; a rough translation would be 'the art and norms of the Igbo people'.

The project also allowed us the opportunity to develop a framework for the interdisciplinary collaboration that was essential for the objectives we had set ourselves. Under the general direction of the late Dr Donatus Nwoga, a professor of English and folk Igbo literature, the project collected information on proverbs, music, oral history, ethnobotany, indigenous biotechnology, ethnomedicine, literature, foods, customs, visual arts and other aspects of life in Igbo land.

Among the important lessons learned from that project was that meaningful community participation is essential for the success of such projects. Organizational innovations were formulated to integrate the efforts of the various disciplines involved in the programme and also to circumvent the traditional bureaucracy and crippling compartmentalization of the administrative structures in academic institutions.

Biotechnology Development Agency

Following the success of the Salvage Ethnography Project and our experience in the evaluation of traditional medicines, in 1989 a group of scientists, non-governmental agencies and the private sector established a consortium to develop a programme of resources management based on the application of modern biological techniques. The approach was to apply modern methodology to the study of traditional biological resources. It was clear to us that a fundamental factor in the threat to African biodiversity is the declining economic value of the environmental resources.

In broad terms, the main objectives of the cooperative programme were to develop methods for sustainable utilization of tropical plants and, more specifically, to collect, collate and codify available information on the uses of African plants, with special reference to indigenous food crops, medicinal and aromatic plants, and industrial crops.

A major aspect of this programme is the KIBORD project, a private sector initiative which, in collaboration with the Department of Pharmacognosy, University of Nigeria, Nsukka, has been investigating tropical African plants as possible raw materials for the cosmetics, pharmaceutical and food flavour industries.

Bioresources Development and Conservation Programme

The Bioresources Development and Conservation Programme was formed in 1991 as the conservation wing of the Biotechnology Development Agency.

It has since become an independent international agency. Its focus is presently on the south-eastern rain forest region of Nigeria, Western Cameroon and the Republic of Guinea. The eastern region of Nigeria presents varied ecological zones; by maintaining biodiversity plots in several areas of the region, we hope to have access to diverse plant species for future drug development work. The programme was designed right from the beginning to address the real concerns of the rural dwellers, whose plight was often linked to previous 'top-down' experiments designed and implemented with minimal input from those whose lives were directly affected. The programme adopts a 'bottom-up' approach in its efforts to empower the poor and powerless rural dwellers to enable them to derive maximum benefits from their environmental resources and their labour.

Three major projects have been formulated under this programme. The first is the compilation of ethnobotanical information from our study area and an inventory of species in the Oban-Boshi-Okwangwo forest complex and the Korup region of Cameroon. The second project is to assess the economic value of the species in the forest complex. The third is the establishment of long-term nature plots to study forest dynamics.

It is perhaps too early to assess the long-term impact of these projects but within the short period of operation of the Bioresources Programme we have observed some tangible results. We do not yet have a finished product but we have begun a process with a clear vision as to its probable outcome. A major difference from similar efforts in other parts of the continent is that the programme was home grown, initiated and managed in its entirety by indigenous staff. It was therefore possible to integrate the decision-making process into the community. Science and technology are viewed as useful tools to be adapted to the cultural framework of productive activities, not as modern alternatives to the contributions of members of the community.

Preparatory to the above projects, we embarked on several activities. First, we hosted an international conference in collaboration with the RainForest Alliance, early in 1993, to address the related issues of biodiversity conservation and the industrial utilization of medicinal plants, at Enugu, Nigeria. The conference attracted participants from several countries and from diverse disciplines, providing local scientists the rare opportunity of discussions with experts in various fields. We started a training programme for ethnobiologists and field taxonomists. The first graduates of this programme will form the core group in our concentric model of building a network of ethnobiologists, field taxonomists and ethnographers. With the help of Shaman Pharmaceuticals Inc., we sponsored one of our ecologists to participate in the first ever training workshop on biodiversity monitoring organized by the Smithsonian Institution, US. We have so far conducted 10 sampling studies and our main ethnobotanical inventory of the region will commence in January, 1994.

Collaboration with Shaman Pharmaceuticals Inc.

The arrangement provides for joint efforts in all aspects of drug development. A joint team of Shaman staff and Nigerian scientists is engaged in a field ethnobiomedical survey. Selected plants are collected directly from the local communities and payment and compensation are effected in three modes. Firstly, a small cash payment is made directly to the informant/collector. Secondly, the community is assisted in its development projects. Thirdly, the medical member(s) of the team consult with the local healers and help them in treating some acute, life-threatening conditions. The international composition of the team helps us in our campaign to popularize the use of plant drugs. What could be more convincing than to have a Western-trained 'European' physician coming back to the village to correct the mistakes of earlier white missionaries.

It is also in our agreement that if and when a drug is developed from any of the leads provided by us, the royalty will be distributed among the informant, the community and the cooperative. The role of the scientists in this arrangement is essentially that of facilitating the contact between Shaman and the healers, not as middlemen or brokers. Because we are involved in all aspects of the drug development process, we are in a position to continue the development of some of the plant drugs as intact phytomedicines if they are found to be active but do not meet Shaman's criteria for future development. Perhaps the greatest impact of this collaboration is on our staff development and capacity building programme. We have been assisted by the company in our training of conservation staff at the Smithsonian Institution and they sponsored two of the lecturers at our first training course for ethnobiologists and field taxonomists.

Tropical Diseases Chemotherapy Project with US Army Medical Command

Life in the tropics is not really the idyllic haven many armchair pundits would like us to believe. Various types of parasitic diseases plague all the countries in the tropics. Unfortunately, because most of the people living in these countries are poor and unable to afford costly prescription drugs, the diseases that affect them are of little interest to pharmaceutical companies. Therefore, while malaria remains the number one killer disease in the world, no new drugs are being developed to treat it. Coincidentally, the US Army is interested in developing new antiparasitic drugs as part of its strategic programme to protect US troops. We have been collaborating with the Walter Reed Army Institute of Research in the development of new drugs for the treatment of malaria, leishmaniasis and trypanosomiasis. We have over a dozen candidate compounds in various stages of development. This project has led to the identification of indole alkaloids of *Picralima nitida* as a new type of chemical in the treatment of chloroquine-resistant malaria and possibly as the first broad-spectrum antiprotozoan agent for the treatment of leishmaniasis and trypanosomiasis.

There is no financial compensation for either the Nigerian scientists or the informants but we are adequately rewarded by the fact that we are developing drugs for the treatment of diseases that affect us. The intellectual rights are retained by us and members of our team have unrestricted access to modern facilities at the Walter Reed Institute.

Biological prospecting

I believe that this paper will not be complete if I do not comment on the current debate about the ethics of biodiversity prospecting. Drug-discovery programmes based on natural products offer one of the most feasible approaches to increase the net worth of forests while standing. It has been argued that while it is important to demonstrate the economic value of biological resources to a country's social and economic development, biological resources are in a sense beyond value because they provide the biotic raw materials that underpin every major type of economic endeavour at its most fundamental level (Oldfield 1984).

Development of drugs based on ethnobotanical leads has followed two paths: the classical approach of identification of single plant species containing biologically active compounds and the characterization and standardization of traditional recipes for reformulation as medicines. The first approach has led to the recognition of many African plants as medicines and the isolation of several biologically active molecules. The second approach, which aims at optimization of mixed remedies as formulated dosage forms, is perhaps more relevant to the needs of the rural populations but has remained largely ignored. Table 1 shows a list of plants that have been considerably investigated and may be used locally in primary health care. The thrust has been to promote plants that provide feasible returns on investment, while little attention has been paid to plants that contribute to the socioeconomic well being of the rural communities.

Most biodiversity prospecting programmes have followed the first model, in which raw biological materials are collected from developing tropical countries with the promise that if new pharmaceutical agents are discovered from the materials so collected, the pharmaceutical company will share the benefits with the donor country. In this scheme, it is expected that the donor country agency or contact will use the proceeds from the venture to support conservation programmes and foster economic development in areas where the product was harvested. Most of the companies participating in the development of plant-based drugs have taken steps to ensure adequate compensation for their partners in developing countries and some have mechanisms for protecting intellectual property rights of the indigenous peoples who provide them with information on plant use. Walter Reid et al (1993) have recently reviewed the various arrangements in place for biodiversity prospecting.

TABLE 1 Nigerian medicinal plants with potential applications in primary health care

Plant	Constituent(s)	Activity/indications
<i>Aframomum melegueta</i>	Essential oil, shagoal, gingerol	Antimicrobial, rubefacient
<i>Ageratum conyzoides</i>	Ageratochromone	Wound healing
<i>Azadirachta indica</i>	Nortriterpenoids	Antimalarial, antipyretic, seed insecticidal
<i>Balanites aegyptica</i>	Steroidal glycosides, furanocoumarines	Laxative, anti-inflammatory, molluscicidal
<i>Bridelia ferruginea</i>	Coumestans, flavonoids	Antifungal, mouth infections
<i>Butyrospermum paradoxum</i>	Fatty acids	Emmollient, anti-inflammatory
<i>Cajanus cajan</i>	Amino glycosides, phenylalanine	Management of sickle-cell anaemia
<i>Carica papaya</i>	Proteolytic enzymes (volatile oils in leaves)	For fevers, antidiabetic
<i>Cassia</i> spp.	Anthraquinone, glycosides	Laxative
<i>Cola nitida</i>	Caffeine, aromatic acids	Tonic
<i>Cymbopogon citratus</i>	Volatile oils	Diuretic, tonic
<i>Dorstenia multiradiata</i>	Leucoanthocyanidins	Antifungal, antiviral
<i>Dracaena mannii</i>	Saponins	Local antifungal, anti-protozoan
<i>Eucalyptus globulus</i>	Essential oil	Local antiseptic, colds, rubefacient
<i>Garcinia kola</i>	Biflavonoids	Antihepatotoxic, antiviral, adaptogen, plaque inhibitor
<i>Morinda lucida</i>	Anthraquinones	Antimalarial, jaundice
<i>Ocimum gratissimum</i>	Terpenes, xanthones	Antiseptic, coughs, fevers
<i>Picalima nitida</i>	Indole alkaloids	Antimalarial, broad-spectrum antiprotozoan
<i>Piper guineense</i>	Lignans, alkaloids	Antimicrobial, insecticidal, tonic, antiinflammatory
<i>Psidium guajava</i>	Essential oils, vitamins	Carminative
<i>Sabiaceae calycina</i>	Alkaloids, flavonoids	Wound dressing, laxative
<i>Schwenkia guineensis</i>	Steroidal glycosides	Oral hygiene
<i>Sclerocarya birrea</i>	Catechins, flavonoids, amino acids	Antidiabetic, tonic
<i>Tamarindus indica</i>	Ascorbic acid, citrates	Laxative, nausea
<i>Tetrapleura tetraptera</i>	Saponins, coumarins	Antiinfective, tonic
<i>Uvaria chamae</i>	Chalcones, terpenes	Antimicrobial
<i>Vernonia amygdalina</i>	Sesquiterpenes, saponins	Tonic, antidiabetic
<i>Xyloia aethiopica</i>	Diterpenes	Tonic, carminative, antiviral
<i>Zanthoxylum xanthoxyloides</i>	Aromatic acids	Management of sickle-cell anaemia
<i>Zingiber officinale</i>	Terpenes	Antihypertensive, anti-histamine

Apart from the serious issues relating to intellectual property rights raised by Shelton Davis (1993), biodiversity prospecting, as presently conducted by many organizations, may be harmful to the long-term interests of indigenous communities in more fundamental ways: for example, the so-called compensation, if not properly handled, could perturb the cultural value system of the community.

Another unsettled issue in biodiversity prospecting based on ethnobotanical leads in Africa is that of compensation of informants and communities that provide both the ethnobotanical information and the genetic materials used for drug development. The pharmaceutical companies are willing to pay only extremely low prices for plant samples. There is also the issue of genetic resource piracy that has been promoted and encouraged by many US, Japanese and European agencies which give supply contracts exclusively to their national institutions. These institutions undertake plant collection expeditions through the services of either herbaria or universities while paying minimal fees for the plants. Because drug development arrangements with transnational pharmaceutical companies may be inevitable for a variety of reasons, an indispensable component of the agreement should be to make a provision for developing local capacity and strengthening the scientific base of the indigenous materia medica.

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DISCUSSION

Balée: You mentioned the identification of indole alkaloids from *Picralima nitida* and their use as antiprotozoan agents. What is the plant used for by the indigenous people?

Iwu: It is used all over west Africa for sleeping sickness, for malaria. In northern Nigeria, it is used to treat cutaneous lesions.

Lewis: Maurice, have you made some arrangement with Shaman Pharmaceuticals regarding compensation for the intellectual property of healers in this long-term process, if something comes out of it?

Iwu: We have adopted a sample form from Shaman Pharmaceuticals. This records the name of the person who supplied the medicine and their village. If there is a profit, 50% goes to the person, 50% goes to the community. In our system, the individual doesn't really have many rights, but we respect the Western system in this.

Lewis: Is your institution in Nigeria involved in any way?

Iwu: I teach at the University of Nigeria, Nsukka. Most of our support comes from grants. At the moment we have not made any money as royalties from drug development. Since 1990, we have had a lot of material support in terms of chemicals and so on from international agencies and corporations. Also, one of our post-doctoral students is going to work at Shaman Pharmaceuticals; another is presently at the Walter Reed Institute in Washington.

Lewis: Is there any direct payment if a product is produced?

Iwu: If there is a profitable product, the individual healer, his community and our organization will benefit, but not the university, because public institutions have no clearly defined guidelines for receipt of direct payment from a corporate body.

King: The people in the different countries choose their own specific arrangements; it is not Shaman Pharmaceuticals' choice to say what form compensation will take. But whenever we discover something and commercialize it, wherever we commercialize or discover it, whether in Ghana, Nigeria or Peru, the profit is returned to the whole group, so that even if the successful product doesn't come from Nigeria, they will still be beneficiaries and vice versa.

Iwu: Shaman wanted to make a cash payment to one of the villages we have been working with. In Shaman terms this was small, but for us it was significant. I went to the village and told them about this contribution. They said that the best use of the money was to support their ongoing communal project.

McChesney: In terms of your focus on tropical diseases, are you using ethnobotanical leads primarily or exclusively?

Iwu: Exclusively. The Walter Reed Army Institute is still doing the studies on the medicinal chemistry and pharmacokinetics of the isolates. We already have the products formulated in Nigeria as a standardized extract.

We are exploring the possibility of securing loans from banks to help establish local phytomedical enterprises. The agricultural loans are more attractive because the interest rates are low. The strategy is to combine the pharmaceutical development with preparing crude drugs for the local populations. It is a continuing exercise and at the moment we are testing only the efficacy and toxicity of the extracts. This is enough to produce some useful results for the people who gave us the drugs in the first place. We are still following the classical drug development protocol and hopefully some day we will be able to isolate the active constituents as pharmaceutical agents.

McChesney: You are using standardized plant preparations?

Iwu: Yes, not pure isolates.

Cox: You believe the African people are avoiding plants of high toxicity. Secondly, you say there is overlap between plants used in diet and those used in medicine within traditional African plant use. Have you looked at diet as a factor in disease causation, for example in malaria?

Iwu: You have to appreciate that in Africa there is a completely different concept about what causes or constitutes a disease and what being healthy means. In Africa, somebody is sick only because they have deviated from the norm. They are not thought to be sick because of an external physical agent; except where there is a naturalistic causation, the spiritual causation is the dominant explanation.

We don't normally use medicinal plants that are poisonous, unless the healer belongs to a special category. Those who have been initiated into the cult are taught about the poisonous plants. The shameful thing is that some ethnobotanical investigators insist on being told about these powerful drugs; these people have not been initiated and they are not supposed to know this. Western medical doctors are respected because they have been initiated according to the rites of their own culture. Such people may be told about the poisonous drugs.

The Calabar bean (*Physostigma venenosum*) was popularly used in West Africa as an ordeal poison, to test whether people are guilty or not. The only people who know how to use the drug are sworn to secrecy. To break the barrier, you have to send someone whom the people will accept as worthy to learn this secret. A new use has now been found for it in the treatment of glaucoma and recently for Alzheimer's disease. When the NIH (through Indena) tried to collect this plant, there was not enough, because in the 1940s the British had banned this drug.

Cox: I am interested in the role of diet in disease, because of the low incidence of antiparasitic plants we observed in our survey (Cox, this volume). Then I noted that, for example, the betel nut has very strong antihelminthic action.

I'm wondering if some dietary elements might have a therapeutic value. Does anyone know of any drugs that have come from plants used in traditional diets, but not as medicines. Secondly, I know that the National Cancer Institute has talked about diet as a possible avenue of cancer prophylaxis; are there investigations of diet as having some therapeutic value after the onset of disease?

Cragg: I think diet is very important. The NCI is placing more and more emphasis on prevention; obviously, nutrition and diet are critical factors in the whole concept of cancer and disease prevention. Various classes of compounds have been developed, for instance the carotenoids and the retinoids in preventive medicine.

Farnsworth: The US Congress appropriated \$25 million for this kind of programme in 1990. This started because of claims that bran prevents colon cancer and lowers cholesterol levels. We received some contract money to study flax seed, which was speculated to have antioestrogenic-type activity. The idea was that eating bread baked with flax meal might prevent breast cancer in women. This project is going on. In the last two years, I've been invited to at least 10 major food companies for 2-3 day workshops, to discuss whether or not they should begin a programme in this area of functional foods or 'designer foods' or 'nutraceuticals'. There is a lot of interest in this. Maybe ethnobotanists should be looking not only at medicinal plants, but also at foods that are different from those usually eaten in the West that may contribute to nutrition and disease prevention.

Lozoya: Professor Iwu, according to our experience in Mexico, one of the big problems in the development of, and the use and promotion of, these herbal remedies is that in Mexico the majority of the plants are not formally cultivated in agricultural industries. Are you working on the problem of introducing the most important of these uncultivated plants into agriculture? How are you facing the production of large quantities of herbal remedies to be used in your country?

Iwu: This is a very important question. Often when you declare that a plant is useful or has a medicinal value, you are more or less signing the death warrant of the plant, unless adequate steps are taken to guide against over-harvesting. We are lucky to have a large pool of highly trained and enlightened forestry staff in Nigeria. We have not had problems like those with *Prunus* and *Pygium africana* in Cameroon and Madagascar.

Proper project evaluation is imperative. In our project on *Physostigma*, we studied its propagation, fruiting and cultivation. Interestingly, the plant thrives only in a deep forest setting. It does well in traditional agriculture where trees are left to provide shade. The seeds are very hard and, according to folklore, the nut has to be eaten by the African porcupine (*Hystriz cristata*) before it splits open to allow seed germination. So availability of the plant depends on the porcupine population in the forest. We are presently collecting the fruits from the wild through local farmers. The project has provided a good example of marrying ecological needs to economic considerations. We have started trial

cultivation of this plant. The project is a difficult one. Since most agroforestry plants need many years to mature, they are not attractive to investors. Cash-flow analysis or the problem of cost effectiveness is a bane to all such projects and will remain so because *Homo sapiens* has become transformed into *Homo economicus* by the successes of the capitalist system. The whole economic order has to be changed. The concept of what constitutes a viable project has to be looked at.

McChesney: A vast majority of the world's population depends upon the use of medicinal plants for their primary health care. We are seeing a selective depletion of these plants. As we discover new Western pharmaceuticals from the same sources, and perhaps even more importantly as Western societies become either for economic reasons or for philosophical reasons more interested in traditional medical remedies, there is an increasing commercial market in those materials. That commercial market may cause the loss of the diversity of those particular species more rapidly than for any other species. We must take care that those species are not singled out for exploitation without appropriate strategies for their maintenance or production. Perhaps more importantly, we need a general strategy to maintain the diversity of medicinal plants that are presently recognized and will be important in the future.

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of biodiversity increases. And all of these increases are proportional to our investment in them.

The outcome is that a smart modern tropical Cabinet explicitly farms and ranches the information in an explicitly designated portion of its wildland biodiversity, just as a smart Cabinet resists pulping its national library during a newsprint shortage or using Internet cables for fencing. And it uses the income generated, in many currencies, to support the management costs of the conserved wildland, further its development, and meet its opportunity costs.

So where are we now? We are at a crossroads. Do we allow the progression of tropical land allocation to conserved wildland biodiversity to continue as has been the case for the past 2,000 years? If so, 10-30% of tropical terrestrial biodiversity will be conserved on 1-2% of the tropics. The locations of this remnant will be the serendipitous outcome of a multitude of social forces acting largely irrespective of biodiversity's traits. One example. There are no unambiguously conserved tropical wildlands of significant size on 'good' agricultural soils. This 'happy accident' strategy for tropical biodiversity conservation will continue unabated if there is no major shift in social attitude. This strategy is quite comfortable for the majority of contemporary individual, national, and institutional agendas in the tropics.

The 'use it or lose it' strategy is the other road. Less comfortable, it envisions 80-90% of tropical terrestrial biodiversity conserved on 5-15% of the tropics. The locations will be the serendipitous and planned outcome of a multitude of social forces acting irrespective of, and with respect to, biodiversity's traits.

The major shift in social attitude that is required by the 'use it or lose it' strategy is that tropical conserved wildlands are conserved for non-damaging use by all sectors of society rather than because they are wastelands, for our grandchildren, for the sake of conservation, crown jewels, biodiversity prospecting pits, observation posts for bar-coded horses, or to fill the agenda of any other single social sector. Each of these seven sacred and reasonable cows, and a whole herd more, become byproducts and ingredients, rather than THE goal - even if each has been of major importance to date, somewhere. This attitude is somewhat akin to recognizing that the value of good agricultural soil or quality roadworks is not in the specific crop or the specific truck, but rather in being a platform on which society carries out a multitude of activities.

The unhidden agenda is to move tropical wildlands into that social category of "so useful to society that no matter what form a society or nation takes, tropical wildland biodiversity will be woven into and through it" - as is the case with health, education, welfare, market economics, communication, etc.

And least someone mistake this essay for the simple

commercialization of tropical wildland biodiversity, please let me emphasize that humanity has won the basic battle against terrestrial nature. Wildlands are rapidly becoming historic events. We are no longer afraid of the dark, spirits are no longer The Cause. We are polishing the globe clean of most large wild biodiversity through species-specific harvest, habitat destruction and contamination. Even the little things - bacteria, fungi, insects, and their brethren - are being removed or thoroughly impacted by these processes.

If we do indeed sweep the battlefield of the wild things, if we do reduce our globe to the playground of domesticates, we consign humanity to the blah doldrums of just that which humans can imagine, invent, and control. The ultimate pabulum. We as thoroughly deprive ourselves as if we excise our color vision, our sense of smell but for frying chicken, our taste but for salt and sugar, our hearing but for high, low and middle C. Your brain is a computer with tens of thousands of applications invented to deal with non-human nature. By the removal of tropical wildland biodiversity we are permanently relegating it to word processing. But the other side of the coin is that our appreciation for superlative architecture does not demand that we have only those buildings that will win international prizes.

Since the emphasis throughout this essay is on 'use it or lose it', there are several caveats, all of which are traditional in other social sectors. They boil down to several equivalent expressions. The frontier is gone. You are always in someone's living room. Tropical biodiversity must escape the Tragedy of the Commons. There is no free lunch. The only sure things are death and taxes.

Applying these age-old concepts to the case at hand:

- the more we know about wild biodiversity, the more we can use it without destroying it,
- not all persons can use wild biodiversity as much as they would like,
- wild biodiversity use must be scheduled and monitored, and
- there are all sorts of users and they pay in all sorts of currency.

Tropical wildland biodiversity needs detailed, knowledgeable and dedicated management as much as does any other social sector.

The more we know about wild tropical biodiversity, the more we can use it without destroying it

What do we need to know?

In order to begin to use wildland biodiversity, we must come to know:

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- what it is..... taxonomy
- where it is..... microgeography
- how to get it in hand..... trapper's tricks & husbandry
- what it does..... natural history

And all of this must come to be in the electronic public domain, because hard copy is not functionally public.

1) We need to know what it is so that we can:

- know it when we see it, and communicate about it today,
- pool and massage our information about it, and
- link what we find out with what others have found out about it.

There is a second and equally powerful reason to know what it is. By knowing what it is - that is, by putting a scientific name on it - the species (or at least a population) is placed within the purview of taxonomy's enormous power of inference, that inference based on relatedness as expressed through grouping into genera and higher taxa, and derived from gene to whole organism similarity. And this kind of knowing demands a specimen- and observation-based database to back up the derivative species-based information bases and knowledge bases.

2) We need to know where it is, or at least where a portion of it is, so that we can get to its location "on call" so to speak. A list of the books in a Library of Congress is of severely reduced use if there is no knowledge as to where the books are, even if they can be recognized and read once in hand.

3) We need to know how to get it to hand or eye so as to get the information that we use or seek from it. All hunter-gatherers and their field biologist counterparts have long experienced the circumstance where a species is known and appears to be absent, yet with the appropriate collection method appears in droves. We also need to know how to get it to hand so that we can care for it and multiply it, so that we can introduce it to the agroscape - rural or urban.

4) We need to know what it does - its natural history in the broadest sense - so as to give us clues as to what it offers by itself and through its interactions:

- suggest how to farm it elsewhere, and
- allow us to know the impact of our presence, studies and sampling.

The first three of these four needs tend to be open-

ended, yet require progressively less investment with time for a given site, while natural history understanding is ever-expanding and peaks later in the cycle of involvement.

Taken in collaboration, these four activities are genuine biodiversity inventory, and they constitute the real base on which biodiversity management is constructed - recognizing fully that management for a given site can be built on one or more activities as the others are being developed.

These four activities can be, and will be, carried out by a diversity of persons for a diversity of agendas in a diversity of sites. However, a tropical nation with species-rich conserved wildlands may well be fortunate enough to have 100,000-plus hectare blocks containing 100,000 to a million species and all their interactions. In such a case, a major type of biodiversity management and development strategy is to select - in the context of a nation's full gambit of users and managers - a site and rapidly inventory all its species. This is an All Taxa Biodiversity Inventory or ATBI. The use of an ATBI to set up a major block of a nation's wildland biodiversity for all users:

- projects a massive block of diverse raw materials onto society's table,
- enjoys substantial economies of scale,
- foments mutualistic gains among executors as well as among users, and
- elevates biodiversity inventory far beyond being a taxonomist's tool or a conservationist's listing.

And when multiplied among countries and firmly networked, a global network of these four advantages of an ATBI can and should be achievable, as has been envisioned through DIVERSITAS as visualized by UNESCO. An ATBI is a major advance over the diffuse and dilute approach currently in play, an approach clearly rooted in the time-honored traditions of curiosity-driven field biology as performed by taxonomists and ecologists.

And why must all this activity be in the electronic public domain? First, in contrast to the past centuries of "public" publication of wildland biodiversity information, which was almost entirely aimed at the very specialized audience of the scientific community, we now have the technical opportunity and ability to put tropical biodiversity information truly in the national and global public domain through world-level electronic networks. Second, the goal of tropical wildland biodiversity management is to imbed it in society - all of sectors of society and not just those with access to scientific journals and reprints. Third, the greater part of tropical terrestrial biodiversity is international; biodiversity is a global effort even if a nation is the primary custodian. What we know, and will come to know, of *Rothschildia lebeau* is based on the aggregation of information from studies in Texas, Mexico, Costa Rica, Venezuela

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and Colombia, among others, and conducted for a multitude of reasons - schoolyard exercises, pharmaceutical prospecting, ecotourism guiding, silk research, insect disease transmission, and religious symbolism. Questions of information ownership, costs and charges - such unfamiliar ground for the community of taxonomists, ecologists and conservationists - have very much in common with the well-worked terrain of ownership, costs and charges for other social sectors such as trails, roads, highways, waterways and airports.

The other side of public domain is the responsibility to actually conduct ATBIs and other kinds of inventories, and the subsequent management and development of wildland biodiversity. Much of what has traditionally been the social responsibility of the traditional academic/museum community on the one hand, and "park guards" or distant government offices in the capital city on the other hand, can be most profitably passed to parataxonomists, paraecologists, biodiversity ecologists, educators, ecotourism guides, biodiversity administrators and other forms of site-based paraprofessionals. There is huge potential in training of residents that neighbor the conserved wildland and live in it to where they can accept the responsibility to carry out non-damaging management and user processes. This transfer of power is also essential to moving beyond what is today largely absentee-landlord management of tropical wildlands.

This transfer does, however, meet with two major classes of social resistance. First, the science community is understandably reluctant to invest the energy and tradition modification that will bring this about without compensation by senior science administrators and by society at large for the widespread benefits that result from such a leveling of the playing field. Second, such a transference of political and economic power to rural areas - decentralization and management horizontality in modern parlance - is theoretically attractive but very difficult to bring about in the face of contemporary vertically organized society. A large, properly managed, conserved wildland dances dangerously close to succession from the federal state in virtually all tropical countries.

What do we not need to know?

I have tried to stay away from counterproductive commentary on other trade routes to the same new world. However, to put the above schema for site management and ATBIs in clearer perspective, I would like to suggest ever so gently a few areas where energy might be more productive for long-term biodiversity conservation if spent elsewhere. These comments are likely to insure my notoriety and thorough expulsion from the ranks of biodiversity biologists. And they do run in direct conflict with the very

human behavior of attempting to mold a newly-emerging activity so that its energy feeds one's own agenda rather than targets the goal that elicited the activity.

We do not need to know:

- how many species there are in the world, in a country, in a large conserved wildland. We already know that there are very many and most are unknown in all respects. That is enough information to get on with knowing biodiversity and setting it up for non-destructive use. It is not shameful that "science" does not know whether there are 10 million, 30 million or 100 million species of organisms, and it is a waste of precious time and human resources to focus on refining this estimate. Would biodiversity be aided for us to know that there are 502,451 species in Costa Rica? Would the Library of Congress be more effective if someone counted all the books or the kinds of books? And I should add, that all these estimates seem to have forgotten the existence of bacteria and the oceans. The count of species in a large biodiversity aggregate is a byproduct, not a goal. What does need our attention is our ignorance of biodiversity as organisms and processes. This ignorance does not imply that the numbers of species per se are of importance, though numerical relationships do play their usual role in sampling community properties.
- the world-level or even national-level detailed geographic distributions of butterflies, birds or big trees (or dragonflies, or tiger beetles, or dung beetles). The world is simply not a sandbox offered to scientists to reorganize as they wish so as to save their favorite higher taxon. The function of biodiversity inventory, as outlined earlier, is NOT to choose sites for conservation. One invests inventory attention on an area that already has been seriously designated for conservation status, with the goal of insuring that status through understanding. The bulk of the significant blocks of conserved or conservable biodiversity in the earth's terrestrial tropics are already known and largely delimited. Where this is not the case, there already exist knowledgeable field biologists and conservationists - national and international - who can quickly set the majority of those limits through REAs and other protocols. What is needed is not more "choose your favorite site to conserve" exercises, but rather a focus of the world's scientific, conservation and user energy on making those 5-15% of the world's tropics into places that society really wants to keep.
- one more set of traditional wildlife management data -

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use to know a huge amount about an area so small that its biodiversity must be treated like the rare book section of the public library.

But for starters:

- all conserved tropical wildlands are islands (or shortly will be), and an ATBI is the beginning of providing a ground zero for asking how its biodiversity reacts to such things as global climate change, pesticide contamination, use, and insularization. Tropical wildlands, fractured into habitat islands with distinctive conditions, will be the sites of a special event that will dwarf anything generated by Pleistocene drying or other global phenomena.

- the known universe of an ATBI site can be a standard for calibration (and development) of any and all kinds of inventory, sampling and monitoring technologies and protocols to be applied to lesser known circumstances for a multitude of reasons. Virtually all of today's biodiversity inventory methods and protocols have been developed in the process of inventory of the unknown, rather than against a known universe.

- the known universe of each ATBI site will serve as foundation on which to construct an extremely diverse array of question-driven ecological, behavioral, demographic, ecosystem, etc. studies. The possibilities are mind-boggling with respect to what sorts of ecological work can be done with a complex habitat where virtually every species can be identified on sight.

- an ATBI site is in effect a well-organized wild zoo, greenhouse and culture facility in which to biodiversity prospect for wildland organisms, genes, and their products. An ATBI will remove the single largest obstacle to really serious examination of large arrays of wild biodiversity for human use. And this information has enormous applied value to the further development of the millions of hectares of screenably developing agroscapes throughout the tropics. A happy agroscapes is far more likely to live in peace with the wildland crop than is an agroscapes at war with itself, a war brought on by monocultures, synthetic product substitution, bored human draft animals, etc.

- an ATBI site is national museum, national library, art gallery, concert hall, national zoo, national botanical garden, national university, etc. for ecotourists and other forms of students ranging from grade-school children to senior citizens. How can we hope to even begin to develop biological literacy for the tropics when wild

a la elk in Montana - on this or that turtle, macaw, tiger or deer. Yes, there are some big noticeable tropical organisms that need a close look - vis a vis the real biological and social context of where they live. But in general it is the other 98% of biodiversity that needs most of our natural history attention. And the attention should be in the context of the society that surrounds and infuses the biodiversity of the focal site, and not in the context of the time-honored initiation rituals of academic titles and institutions. Lets stop making conservation science be the science of trying to figure out how to demonstrate that biological research should be funded as a resolution of the biodiversity crisis.

- we do not need to know where each individual of every species is (or was) over the surface of the tropical landscape. Far more than in extra-tropical habitats, the living dead and the population fragments sprinkled across the tropical agroscapes are slated for the dust bin. We have long been deceived by the ability of extra-tropical species to persist as minute fragments in severely impacted landscapes. Ninety percent of North America's biodiversity can survive in a scattered and porous network of small reserves and marginal farm-land/ranchland. The analogous lifeboat in the tropics would do well to save 30%. Our tropical resources, always in short supply, should be directed at saving the bulk of biodiversity in a few large and well-distributed blocks, hopefully robust in the face of climate change through their elevational and multi-habitat diversity. This comment is not meant to denigrate the small patches and fragments of widespread tropical species and the occasional isolated endemic - at times of high value to their immediate owners and neighbors irrespective of their eventual demise or major impoverishment - but rather meant to suggest that we coldly practice a biologically realistic triage so as to bring conserved wildland biodiversity into peace with tropical society at large and more specifically, the agroscapes.

What do we do with biodiversity once we know something about it?

Once one begins to be familiar with the biodiversity package in a large conserved tropical wildland - what does one do with it? This is somewhat akin to asking what does society do with the Library of Congress, Internet, a university, the Missouri Botanical Garden, a supermarket and Disney World all tied up in one. Everything. And this reply stresses the importance of conducting an ATBI on a very large area, an area large enough that it can be multi-used without the users destroying it. It is of much restricted

nature appears as a homogeneous green wall, when its incredible array of solutions, questions and examples are illegible and undecipherable?

- an ATBI site can be a major provider of ecosystem services, especially if the site is chosen with that as an additional criterion, and simultaneously be well enough known to study the internal mechanics of ecosystem services.

Priority Knowledge

Today we are in the throes of determining how to record, manage and transmit wildland biodiversity information - database structure, networks, distributed databases, image transmission, authority files, authorship attribution, bar coding, retroactive data capture, OCR the literature, etc. - but tomorrow these technologies and protocols will have been resolved for the most part. And then, and for centuries thereafter, the resource in short supply will be the biodiversity information itself. Who eats what, what breeds when, why is this pond green and that blue, when will the mushrooms bloom, when are the birth peaks? What genes code for magnesium resistance, for morphine synthesis, for dry season dormancy, for sex? What does a complex tropical ecosystem do when the annual rainfall declines 40%? How ironic that just as the great bulk of tropical humanity flees the countryside or polishes it clean, humanity is coming to have the wherewithal to recover forever what some grandparents knew, and the grandchildren will want to find out, about the vaporizing wildlands. How ironic that the wad of indigestible and unexportable information on specimen labels in the world's natural history museums may turn out to be less valuable than tidbits of natural history gleaned from local naturalist's publications, birdwatchers' notes, and school yard exercises.

Are we going to shed our distorted visions of tropical biodiversity gained from centuries of touristic field biology, and really begin to offer society an understanding of biodiversity in its heartlands? You know what is a keystone species? It is a species that you know enough about to recognize the ripples that occur when it is removed. All species are keystone species on some scale, though not necessarily on the scale and ruler of a 1.6 m tall diurnal vertebrate. We need to look at more than our big wooly relatives. What is a redundant species? One that does not yield what you want. This is not a biological trait Indicator species?

Any species can be a miner's canary in the right circumstances. Please let us leave the Holy Grail for other social sectors.

Computerization

The all-invasive wave of computerization is a quantum and qualitative change in the acquisition, massage, distribution, and archiving of biodiversity information. It will change humanity's relationship with biodiversity more than has the printing press, the camera or the chainsaw. Computerization is a great part of what allows the realization of all the prognosis mentioned or alluded to here and elsewhere in biodiversity management. For the first time in human history, there are the opportunities, and the beginnings of, open and massive intra- and inter-society flows of biodiversity information, something that was alluded to through "publication" but in fact not even minimally achieved as compared to what is to come.

For the first time it is possible for an individual and a site to acquire, massage, distribute and archive the unimaginably large quantity of highly particulate information - images, specimen descriptors, species descriptors, habitat descriptors, circumstances, previous knowledge - that is pertinent to the management and use of a conserved wildland that contains hundreds of thousands of species and (is being) worked on by tens to thousands of observers over the years or even at one time. The essentiality of bar-coded uniquely tagged vouchers and specimen-based information becomes self-evident. The primal necessity of attributing authorship and evaluating input for all this data is written in stone. The real art is how to massage information and put it in a multitude of formats for a multitude of users. The real biodiversity question then becomes whether the developed world is willing to accept the leveling of the global playing field that all this represents. And most evident of all, the last thing biodiversity management needs is new hard copy journals, more hard copy books (except as temporary reports for some kinds of field convenience), and more continuation of the stultifying hard copy biodiversity information management traditions of the past several centuries. What tropical wildland biodiversity management needs is for all the holders of biodiversity information to get that information as fast as possible into the Internet, rather than waiting decades (if ever) to see it frozen onto thin sheets of wood.

What is taxonomy?

Taxonomy is basic technological and philosophical infrastructure for wildland biodiversity management. Without taxonomy there is no inventory, no collation and distribution of information in space and time, no inference among species. But taxonomy, like conservation, ecology and other specialty areas, has evolved to its own drumbeat. But most encouragingly, taxonomy is currently re-examining its mission through efforts such as Systematics Agenda

2000 and a multitude of international symposia. US government agencies are beginning to take and support a global responsibility in taxonomy, and taxonomy is once again coming to be supported as a form of national development.

Some things are evident in the changes that biodiversity management asks of taxonomy. No more turgid keys, please. Expert systems, picture keys, Intkey, and the like are a major step forward. Give top priority to the coming together of taxonomic and specimen data standards, data models and computerization userfriendliness. Where we all need to be headed is identification guides that are largely flipping through an electronic (or hard copy) picture book, with centralized or networked processors to where an image or discussion of a doubtful organism can be sent for taxonomic confirmation. Close on our heels is the magic box into which a bug is dropped, sequenced, sequences compared with a library, and a name spit out if it matches. And then, with the name in hand, one calls up what the greater global network already knows about the biology and biodiversity of that species - a global field guide in a pocket. Once again, it is the genetic and biodiversity information that becomes the resource in short supply.

And where is very much of that information pool today? In the heads of retiring taxonomists. Speaking quite coldly, these most honorable systems should be databased, information based and knowledge based - the brain dump - to say nothing of put diligently into mentorships for the next generation of those who will manage this (to date) highly personal tradition. This information capture might well be done in conjunction with the retroactive data capture of the world's large museums, but if not, the highly perishable should be given priority over the embalmed.

Taxonomy is really a taxosphere with nodes of specialists, collections, and hard copy data - all strung together on an Internet lattice and variably plugged into the world's biodiverse sites. The nodes are interconnecting as much for taxonomy's own work as for all the other users of biodiversity. There is a major question as to whether, and to what degree, it is worthwhile to retroactively capture the information in museums. Ironically, museums were on the one hand the expressions of interest in species as manifest through specimens (and museum information therefore often not gathered in a manner as to be of maximum use in biodiversity management), and on the other hand they are the depositories of the raw material on which taxonomists have largely built their science. To someone concerned with a given conserved wildland, the international and national distribution of a species (as recorded on selectively and serendipitously collected museum specimens over previous decades) may be of limited interest. What may be of much greater interest is whether and where that species occurs today within one's local or national gambit of

interaction.

At the very time when extant museums are re-thinking the value of their collections, they are the logical recipients of the new and enormous responsibility of curation of the mass of voucher specimens that will appear in biodiversity management. These specimens are perhaps of lesser direct taxonomic interest, but of huge importance in underpinning a mass of biodiversity information, and a base on which much more will be built. We find ourselves in the ticklish position of explaining to the tropical world at large that the specimen has little or no value per se, and thus should not be the focus of nationalistic possessiveness, while at the same time it may be a voucher specimen or genetic information source that merits long-term maintenance costs. And the more the gene jockeys tell us, the closer that specimen becomes a legible cookbook for many of the things that it did in nature.

The taxosphere has had a long run on the engine of personal interest in organisms by taxonomists and other kinds of field biologists, rather than on a true economic and social recognition of the critical nature of taxonomic underpinning and guideposts for biodiversity use. To the degree that society neglectfully accepts that taxonomy is run by such a volunteer work force, we are confronted with the advantages and disadvantages of trying to run an army or national park staffed with unsalaried volunteers, even very competent ones. While the taxosphere needs to reach out with joy for the finances and responsibility that should come with a reversal of this trend, this same taxosphere is then confronted with an increased accountability to the funder, a kind of accountability not usually associated with those who operate in a free-spirited and artistic social sector.

It will be most helpful if the taxosphere can manifest some self-directed willingness to spread responsibility to those taxa and technologies previously unconsidered, as a response to society's willingness to put resources behind this action.

Small stuff

The bulk of biodiversity is constituted of very small organisms - easily 80% of a conserved wildland's biodiversity weighs less than a few grams even as an adult. However, the traditions of taxonomy, information management, field ecology, species use, conservation, wildland education, and species evaluation of wild biodiversity have been impacted hardly at all by the biology of the small stuff. On the other hand, the enormous biodiversity of small species constitutes much of the use potential in biodiversity and offers a huge part of the management complexity for this biodiversity.

This means that finding out which biodiversity is in a

site and getting it in order for society will contain a very large element of field taxonomists and biodiversity ecologists spending their time getting their (easily inventoried) big organisms into situations where they can be poked and searched by the people who work with viruses, bacteria, fungi, mites, small insects, protozoa, parasites, algae, etc. This means that the quality of laboratory facilities on-site will need to take a megastep upward to complement the old tent and machete. And this means that the conserved wildlands will be brought yet closer to society.

Not everyone can use it as much as they would like or in all ways they would like. As I mentioned at the outset, the frontier is gone. Wildland biodiversity use must be scheduled, planned, monitored. And there will be all sorts of users, and they will compensate for their impact through payment in a very wide range of currencies.

It is no secret that tropical wildland biodiversity is currently threatened by the nearly invisible symphony of a multitude of threats that are exponentially gaining force from unseen and unexpected directions. They impact simultaneously in different countries, and the well-established lack of inter-country communication renders them even yet more invisible. That little guy in the forest with his chainsaw is now unexpectedly given a huge boost by the fall of trade barriers, by pharmaceuticals abruptly rendering yet another major tropical disease less of a barrier to wildland clearing, by the introduction of newly gene-jockeyed domesticates, and through speeding the process of domestication through gene-jockeying. Knockout punches are gathering silently in the wings. Yet the left hand needs to be doing something quite noticeable before the right hand takes note. Conserved wildlands require aggressive and eager succor from society at large if they are to survive the very onslaught that is often generated quite innocently by that same society.

But do extinction rates really matter? Does it matter if this or that species goes extinct? Try it on the other way around. We will lose 10-20% of them. So, let's get busy delimiting the areas that will be conserved wildlands, largely forget about those things that live outside, and get on with making very high quality conservation areas of the 5-15% of the earth's surface containing the remaining 80-90% of the species. And make very high quality agroscares and urbanized habitats in which these areas are imbedded.

All the mental energy and all the funds put into anguishing over the losses could be far better spent on quality survival of the survivors.

It might be useful to note that the current extinction differs from the Cretaceous extinction largely in that:

- we are not going to give the terrestrial world back to biodiversity to re-evolve after this is all over,
- we will have reduced terrestrial biodiversity to tens of

thousands of Galapagos Islands and New Guineas, where speciation and higher taxon evolution will work apace (and generate a plethora of endemics), and

- the surviving subset of species will be area and habitat defined - rather than being ecological groupings such as those small vertebrates that could aestivate or stay warm (microherps, micromammals, and feathered hotblooded microdinosaurs) and survive on a diet of plant and animal carrion, seeds and other dormant organisms, and on the insects and fungi that feed on the same.

So the very first self-denial that must become characteristic of biodiversity users and practitioners of biodiversity management is the temptation to have different government agencies and NGOs harvest their own biodiversity information and just wield it to their own end. We are hopefully about to enter into an era of interagency and inter-NGO cooperation, with the Oaxaca Declaration, the US NBS, much inter-museum collaboration in database development, and databases moving onto the Internet as recent examples.

ATBIs, INBio-like institutions, national biological surveys, and the Internet itself are all manifestations of this process of user collaboration.

As alluded to earlier, terrestrial conserved wildlands are habitat islands, and will become more so. They are habitat islands joined only by a selected few (largely) aerially mobile organisms and positioned in an ocean of intensely managed domesticates. This insularity means that no matter how large and how well-planned and inventoried, each conserved wildland will have a different and heterogeneous ceiling for intensity (impact) of on-site users. We even have the irony that established conserved wildlands can render the concept of "endangered species" an anachronism. If they are in truly conserved wildlands, they survive in those habitats at their naturally achievable densities or they go extinct. Outside of the conserved wildland, they are basically forgotten. Yes, of course some will survive as society's pet trees and animals, or as domesticates and weeds, but these are not the focus here. The question is not whether we can bustle about the countryside feeling valiant in the protection of the living dead, but whether we can design rules for maximum non-damaging use of significantly large conserved wildlands and tempt society to live by these rules. Let's use our energy NOW to make them better islands, rather than dream that we are being effective conservationists by saving a noble tree left standing in a tropical bean field.

Introduced organisms would seem to be a sort of unconscious use of conserved wildlands and marginal farmland. First, please stop the introductions until the sink as a whole has been taken into account. No matter how many firewood trees have been cut down in Africa or India,

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the solution is not the introduction of new species of firewood trees from the Neotropics. No matter how little water can be allocated to Hawaiian home ornamentals, the solution is not the massive introduction of Costa Rican dry forest drought-resistant plants to Hawaii.

Second, recognize the extreme biodiversity contradiction. At least on mainland habitats of broad extent, virtually every organism in the natural community evolved as a little population somewhere else. It is an immigrant most of where it is found today, and mainland wildland biodiversity packages are mostly put together through ecological interactions rather than through on-site evolutionary fine-tuning. The horse is instructive. The horse is a New World native and could be argued to be a proper part of Mesoamerican conserved wildlands, albeit with a machine gun to substitute for the sabertoothed cats.

The fact that the horse was kept alive in the Old World while we extinguished it in the New World and then reintroduced it, is really not that different from reducing the North American bison to a tiny herd and then building it back up (and partly domesticating it as well). Use needs to be measured by real impact, not by the license plate of the 'immigrant'. All wildlands are strongly human impacted already - extinction of the Pleistocene megafauna, extinction of contemporary vertebrates, global warming and other change, hunting, roadside secondary succession, introduction of bacteria, fungi, mites, herbs, etc. There is no 'pristine' nature, free of 'introduced species' and human influence, to conserve.

Once designated as conserved wildland for the non-damaging use of its biodiversity, this land use categorization needs to be inviolate. In this respect wildlands conserved for their biodiversity are qualitatively different from other kinds of land use, and not easily interchangeable with other kinds of land use. That is to say, the agroscape can easily move from peanuts to sorghum to cows to peanuts over the years, but moving a given hectare from rice to forest to rice to forest requires considerably more cost and long range structure. However, the latter does offer enormous potential in the siting of conserved wildlands throughout the tropics.

A conserved wildland is far more context-sensitive than is an equal-sized portion of the agroscape, and a conserved wildland cannot afford to go bankrupt - unless society is also willing to just leave it in peace until wildland production starts up again. In the same vein, we must come to recognize that a conserved wildland is no more or less responsible for contributing to a country's national budget and the solution of its social ills than is any other kind of land use. That is to say, a successful rice farm is not held accountable for the social welfare of all its neighbors, except through some variety of national tax income distribution, and there is no reason to expect the earnings of a conserved wildland to be responsible for the solution of all

its neighbor's ills except through the same kind of distribution of earnings, employment opportunities and taxes.

Direct site use by people is, ironically, perhaps the easiest of all facets of biodiversity use. On the one hand, society at large, and specific individuals, are very good at using/visiting a conserved wildland area to the level of intensity allocated, if they are informed and if the method of explanation is clear and cast in a socially perceptible format. This communication requires more or less direct human presence and interpretation, depending on the society and circumstance. On the other hand, the more specific harvesters - researchers, staff, biodiversity prospectors, inventories, ecosystem service personnel - are likewise proving themselves to be socially highly responsible in conserved tropical wildlands if they find themselves cast in a responsibly managed and forward-directed interaction between society and biodiversity. But we can never forget that the finest farm or ranch can easily be destroyed through overgrazing of pastures, improper irrigation, failure to crop rotate, poor selection of landraces, sloppy agrochemical application, etc. Wildland biodiversity is another kind of farm or ranch.

Throughout the tropics, lured by the ecotourism dollar, there has been a very strong tendency to use the dollar as the primary currency in valuating conserved wildlands. While this has its good points, what seems to be forgotten, largely through the inconvenience of leveling the national social playing field, is that the "poor" national user of a conserved wildland pays in votes (as well as through some decentralization of cash flow) and in emotional attachment to the conserved wildland. When the 4th grade schoolchild is voting on the irrigation district board as a 55 year-old adult, that person will remember what was learned in the conserved wildland, what experiences were had there, and visualize the grandchildren as doing the same. And this phenomenon is reinforced when the conserved wildland and its associated processes constitute a major local employer, spends millions of dollars per year locally in operations costs, and uses its income to establish its own management endowment.

Equally revealing, and long-term, is the biodiversity prospecting loop. When a conserved wildland or its facilitators bring home the first biodiversity prospecting contract, the returns seem very large as set against the background of tropical conserved wildlands as all cost and no visible income other than piddling ecotourism entrance fees. However, the Ministry of Natural Resources really will take notice when, if ever, the first actual royalties from a drug discovery flow into the national budget for conserved wildlands, or better yet, into the endowment fund of the conserved wildland from which the raw materials were collected. But even then, the Ministry of the Economy will not take notice. That will occur when the pharmaceutical

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company decides to move some substantial portion of the development process - \$200 million-plus per successful drug - into the source country. Once again the leveling of the playing field reappears, with all its advantages and impediments.

The art of valuation of non-destructive use of biodiversity rests heavily on being able to work in many currencies, to recognize the market value of information to many different sectors. A field guide to the birds of a tropical country is not just "a book". It is essential technology in the ecotourism industry. It is fertilizer for the ecotourism crop. Yet also, without a conserved wildland in which to observe the birds and the things they do, it becomes just a book. That is to say, the value of biodiversity information is extremely context-dependent. A country may "have" (really, be custodian for) the most marvelous set of endemic species or bizarre habitats, but if the information they contain and display is not put into various social currencies, those species and habitats will contribute little or nothing to their very survival in a human-dominated globe.

And all of this can do nothing but re-emphasize the critical need for institutions and processes that accept the responsibility and challenge of the specific task of gathering, collating, massaging, and distributing biodiversity information from and about a nation's conserved wildlands. This essential process must occur at the level of each specific wildland and at the level of the national synthesis, at the least. You, society, can hardly be expected to value that which is invisible to you. Ironically, the very salvation of biodiversity - its valuation by society - is a multi-edged sword.

First, if the area is conserved for its value on just one or a few axes, then it is in the same risk zone as the country that depends on a monoculture agroscape - coffee, bananas and Costa Rica are close to mind. Fortunately, wildland biodiversity is in fact far more diverse than is the agroscape and as such, crop diversification as well as market diversification is very feasible (though hardly begun to be developed).

Second, information differs from agricultural produce in that one consumes produce today and needs more tomorrow. Information once consumed is public domain and continually widely available, and even more so in the electronic and computerization age. Therefore a given piece of new information is not likely to have nearly the same value in next year's market as in this year's market. There is, so to speak, a very high premium on very rapid product development, almost as one encounters in the news business. However, as in the news business, naive consumers of biodiversity information do continually appear through human biological processes (birth, forgetting, nostalgia) and the amount of absolutely new biodiversity information to be gathered and developed is certainly limitless for many

decades to come. Biodiversity information can also become 'new' by having a new use appear.

Finally, it is no secret that a nation's conserved wildlands are its package of local landraces. All that a nation does to both share and profit from the landraces in its agroscape is pertinent by analogue to the treatment of the breeding stock and genes from its conserved wildlands. And just like petroleum, which occurs in a multitude of countries, the value of any one of these species depends on what the country constructs on top of its national supply of this basic raw material.

Any conserved wildland will need to struggle with the question of physical use and the impact of sampling, observing, studying, experimenting, visiting, etc. Given that all conserved wildlands are in fact impacted already by humanity, and always will be, the question is basically what level of use falls within the "natural" ups and downs and expansions and contractions of behavior and demography and interactions. What level of use is 'non-damaging'. That is to say, any user does leave a footprint or a beer can if one knows enough biology to see it. However, just as the tapir nibble out of the top of a bush blurs into biological "noise" within a few days to weeks, the biodiversity prospecting sample from that bush does as well. Just as the loss of the annual agouti kid to a boa constrictor changes the mother's foraging pattern for a year, the monkey-watcher's trail changes the sleeping site of the local peccary herd. But the next year both perturbations are indistinguishable from the multitude of other non-anthropomorphic changes.

At present, perhaps the largest single near-sighted user of tropical biodiversity is the developed-world academic and museum community. And in what currency will they pay for and value their use? For long we have cast our graduate students in our own image, and now and then done the same to one from a tropical country. But it is not at all clear that this is the kind of payment we would make if we were to really think out what a tropical resident needs, for example, to be part of the biodiversity managerial cadre. Even more basic is whether we should be expending so much energy on producing yet more graduate students in a steady state system, or expending that energy in collaborating with the tropics as it comes up to speed. We are letting our lifestyles in our developed world culture define the way that we examine and study tropical biodiversity. That is OK, more or less, if the biodiversity is in our backyards in Minnesota or California, but it definitely is not if the biodiversity is in Madagascar or Colombia and we live in England or Illinois.

The upcoming presidents of tropical countries will often have advanced degrees from universities in the developed world as well as from those in their home countries. Will they have learned about biodiversity around those northern

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universities? Or will they have learned how to deal with the biodiversity situation in their home countries, a situation that desperately needs their political attention? Costa Rica's new president Jose Maria Figueres (1994-1998) has accepted the challenge of steering his country in the direction of sustainable development and management of conserved biodiversity for society's non-damaging use. Has his university training, and that of his advisors, prepared him for this?

A peculiarity of taxonomy and natural history - those pivotal professions in biodiversity management - raises its hand here. As mentioned earlier, taxonomy and natural history are one of the very few subsectors of science very strongly based on people - amateurs and professionals alike - who really love the actual objects of their research as well as being intensely curious about them as objects. High quality biodiversity managers - wildland and urban, taxonomists and many other kinds - are largely born and then facilitated, just as are musicians, politicians, scientists, basketball players, etc. The expression of their genes requires social openness, and the facilitation of their abilities costs money and job security. Retooling people and institutions from other areas for biodiversity management has the usual advantages and drawbacks, with institutions being the most difficult. Who is going to crawl around in the hot tropical sun doing natural history without being in love with the organisms? That is to say, who is going to spend 50 years of their life peering intently at some 1 mm long organisms in return for just salary and prestige? We would do far better to feed and support those who are by nature inclined in this direction, as we do with musicians and many other professions, than to issue a call for all good people to come and be good taxonomists and natural historians. They won't be. But we can reinforce those with a propensity in this direction, and draw out the best in them.

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SECTION 4

BIOPROSPECTING SCIENTIFIC PROTOCOLS

SECTION 4: BIOPROSPECTING FRAMEWORKS AND PROTOCOLS

Introduction:

In this section, the bioprospecting framework employed by INBio and a series of protocols are presented. The first paper gives an overview of INBio's bioprospecting strategy. The papers that follow present the process of bioprospecting, from sample collection to database development, including its relation to INBio's other programs. The extraction protocols included here describe the chemical processing that takes place in INBio's extraction laboratory as a tool for adding greater value to bioprospecting samples and increasing Costa Rica's technological and scientific capacities.

The paper entitled "INBio's National Biodiversity Inventory" sketches the Institute's "parataxonomist program" which employs local community members to collect inventory samples in a novel manner. Parataxonomists are people originating from the towns surrounding the Conservation Areas who have been given a stake in the conservation and sustainable development of their nation. They are both inventory collectors and local educators who initiate the inventory process later completed by technicians and curators back at INBio.

The Inventory Division is the mechanism responsible for discovering what biodiversity exists in Costa Rica's protected lands and where it is located, information that supplies the groundwork for sustainably using biological resources. While the Inventory Division does not catalogue Costa Rican biodiversity for bioprospecting *per se*, and therefore does not collect samples for bioprospecting activities, the taxonomic information generated from collecting inventory specimens is shared between the Inventory and Prospecting Divisions to provide the basis for establishing the ecological leads used in bioprospecting sample collection. Bioprospecting collectors, "bio-ecologists", are biologists and chemists stationed in the field to collect samples for extraction and the relevant information on ecochemistry and natural history for natural product research and development.

Note that the Biodiversity Inventory is the single most expensive component of INBio's program. Fully 34% of INBio's budget is devoted to the inventory and the concept that biological diversity must first be known and described before it can be utilized sustainably. In light of the expenses incurred, it may be more efficient to adapt preexisting biological inventories, for example those funded by the Global Environmental Facility, for multiple uses. Raising the initial capital for bioprospecting is challenging, so using preexisting inventories can be one mechanism for lowering the cost of this initial investment.

The final paper reproduced here describes a study conducted by scientists at the U.S. National Cancer Institute in which various organic solvents are compared for their efficacy in extracting organic molecules for bioprospecting.

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Insect Extraction Protocol

Microbiology Laboratory

Extraction of Bioactive Molecules from Plants. By Thomas McCloud, Josef Nemeč, Gary Muschik, Harley Sheffield, Paul Quesenberry, Mathew Suffness, Gordon Cragg and Janice Thompson

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INBIO'S BIODIVERSITY PROSPECTING PROGRAM: GENERATING ECONOMIC RETURNS FOR BIODIVERSITY CONSERVATION¹

by

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Biodiversity prospecting is nothing new; humanity has always used biodiversity. What is new is an innovative approach to prospecting activities sharply veering away from the inequitable relationships of the past in which traditional prospecting activities tended to exclude resource rich developing countries from the economic, technological and scientific benefits to which they are entitled. As one example of this, the Instituto Nacional de Biodiversidad (INBio) is negotiating agreements with scientific research centers, universities and private enterprise that are mutually beneficial to all parties. These pioneering agreements provide significant returns to Costa Rica while simultaneously assigning economic value to natural resources and providing a new source of income to support the country's Conservation Area maintenance and development costs.

To accomplish this, INBio is working in partnership with pharmaceutical, biotechnological, agroindustrial, cosmetic industries, to collaboratively explore the tremendous biological wealth INBio's Inventory Program is uncovering. The Prospecting Program's objectives include (1) facilitating society's sustainable economic use of biodiversity by establishing collaborative, market-driven research and development activities; and (2) generating income to support biodiversity

¹ This presentation has been adapted from the conference "Biological Diversity: Exploring the complexities" University of Arizona, Tuscon, USA 25-27 March 1994 and the document currently in press: *Their Seed Preserve: Strategies for protecting global biodiversity* McNeely and Guruswamy (eds.). Duke University Press for "A Practical Workshop on Biodiversity Prospecting for Cameroon, Madagascar and Ghana", INBio, Heredia, Costa Rica, April 22-May 3, 1995.

conservation through donating 10% of prospecting research budgets and 50% of any future royalties received by INBio to the country's Conservation Areas.

Over the past four years, the Prospecting Program has developed considerably, carefully pinpointing the key elements for negotiating successful collaborations. INBio's experiences thus far demonstrate the multi-sectoral and multidisciplinary nature of this activity. Biodiversity prospecting requires the creation of appropriate frameworks and the cooperation and involvement of governments, intermediary institutions, private enterprise, academia, and local communities and entities. This activity also requires the incorporation of lawyers, lawmakers, scientists, managers and economists from developing and developed countries.

◆ THE FOUNDATION OF BIODIVERSITY PROSPECTING FRAMEWORKS: MACRO-POLITICAL ISSUES

The fundamental point of departure for a biodiversity prospecting framework is *macro-policy*, the set of governmental and international regulations, laws and economic incentives determining land use patterns, access to and control of biological resources, intellectual property rights regimes, technology promotion, and industrial development. Macro-policies are formed on the international, national and social levels.

A. The international spectrum

On the international level, agreements, conventions and other mechanisms establish the relationships and protocols for biological-genetic resource sharing between countries. A number of the more significant international conventions, agreements and organizations defining the international arena for biodiversity conservation and natural resource use include the following:

1. The 1940 International Convention on Nature Protection and Wildlife Preservation in the Western Hemisphere, prohibiting the exploitation of national parks, set the stage for the access to and control of resources, setting aside designated areas for environmental protection.
2. Forty years later, the 1992 Convention on Biological Diversity created new guidelines for international conduct regarding natural resource use:

- calling on 157 countries to create national frameworks for regulating access to and control of resources, intellectual property rights, environmental protection and commercial laws.
 - The Convention required these frameworks to be harmonized with goals of development, conservation and the fair and equitable sharing of benefits derived from the sustainable use of biological/genetic resources.
3. The United Nations World Intellectual Property Organization (WIPO) currently establishes the regulations that define what is considered intellectual property and patentable, aiming to consolidate these international definitions on a global level.
 4. Similarly, the Trade Related Intellectual Property Rights (TRIP'S) of the General Agreement on Trade and Tariffs (GATT), formally approved in 1994, establishes regulations surrounding the *commercial* use of intellectual property, and equally attempts to harmonize its commercial applications on the international level.
 5. Other fundamental mechanisms, such as parts of UNCED and the United Nations Working Group on Indigenous Populations Draft Declaration on Indigenous Rights are presently attempting to address the more difficult and amorphous issues of indigenous community rights and applying intellectual property rights to those communities or individuals.
 6. Sub-regional agreements, such as the North American Free Trade Agreement (NAFTA), the Amazonian Treaty, and the Pacto Andino, introduced an important element to guide more specific instances of international relations regarding resource protection and use, unifying policies in regions sharing common resources, political and economic paradigms.

These mechanisms, in addition to many others, are broadly defining the international arena regarding resource access. Nevertheless, conventions, agreements and organizations have still left responsibility of designing adequate legislature and the regulations to each individual country, creating instances problematic for some, beneficial for others.

Lack of laws and precedents to guide national policy makers has led to difficulties largely because the language employed is often not specific enough to elaborate legislative details if there is no preexisting foundation upon which to build.

At the same time, however, open interpretation has provided broad backing while simultaneously allowing countries enough room to freely create new laws based on existing experiences.

B. The national arena

On the national level sovereign governments determine the macro-policies that deal with issues such as land ownership, land tenure rights, the creation of protected areas, biological-genetic resource use, nationally recognized intellectual property rights, the definition of public-domain resources, and the creation of market incentives or deterrents for private enterprise and research investments.

1. *Incentives*: where they already exist, clear laws and regulations regarding land ownership and access to resources are conducive to collaborating on research activities.
 - such incentives promote in-country partner stability and maneuverability attractive to private industry and academic and scientific research counterparts, on the one hand, while
 - creating industry incentives by way of governmental mechanisms advances the important objective of national economic development as a component of prospecting activities.
2. *Deterrents*: national policy vacuums and outdated legislature existing in many countries create disadvantages:
 - difficulties in elaborating legislature where no precedents exist.
 - question of how to enforce new legislature.
 - obstacles in rewriting existing laws and regulations to accommodate changing global paradigms.

For example: Costa Rica has largely benefited from a strong set of national policies that include:

- the protected status of a quarter of the country and the presence of laws and regulations regarding resource access and use such as the Wildlife Protection Law of December 1992.
- strong backing for Costa Rica's national policies provided by diverse international agreements, organizations and other mechanisms have permitted organizations such as INBio to successfully advance collaborations with private enterprise, academic and scientific research counterparts.

C. Supportive macro-policies in the social sector

Together with the heavy investment in education and other social services, Costa Rica's macro-policies have created an scientific environment of qualified institutions, researchers and educated personnel appealing to private enterprise agreements.

◆ BUILDING ON TO MACRO-POLICIES: INVENTORIES, BUSINESS DEVELOPMENT AND TECHNOLOGY ACCESS

Supported by a favorable international and national macro-policy, INBio advocates including three basic elements to guide the rational use of biological resources in prospecting agreements: biodiversity inventories and information management, business development, and technology access. These elements also contribute to creating more attractive business partners and increasing bargaining leverage.

A. Inventories and information management

Biodiversity inventories and information management become a crucial step in creating Biodiversity Prospecting Frameworks, creating a base of knowledge fundamental to prospecting activities. Biodiversity inventories, through the development and management of biological, ecological, taxonomic and related systematic information on living species and systems, increase the value and promote the sustainable use of raw biological resources. INBio's experiences also indicate that the information based system underlying a biodiversity prospecting program is considered an asset by research collaborators:

- creates catalogs of available resources and their location.
- prevents damage to ecosystems, areas, species or populations by indicating what resources are available, and where they can be collected without damaging ecosystems.
- in-country collaborator becomes a more attractive, knowledgeable, reliable business partner.
- reduces researcher investment risk of collecting more material if necessary.

Information shared between inventory and prospecting programs results in an "information service" that increases the in-country collaborator's overall bargaining leverage by decreasing private, academic or scientific research investment risk and adding value to raw materials. This information service can take many forms

ranging from taxonomic data and research findings to traditional knowledge. Additionally, inventory activities can either be directly associated with prospecting programs, or operate as a separate activity whose information supports the prospecting program activities.

B. Business development

Building on inventory based knowledge of what natural resources are available and where, business development defines markets, market needs, major actors, national scientific and technological capacities and institutional strategies and goals.

1. *Knowledge of one's assets and debilities*, and properly marketing them, is vital to negotiations. Logically, knowing what in-country skills and capacities are available is helpful for establishing institutional and national goals that include the acquisition or development of information, technology, and products that increase the value of samples, augment existing capabilities, and advance national development (including economic development).
2. *Using market surveys* to identify potential economic users and elaborate research collaborations complements in-country evaluations by pinpointing prospective collaborators capable of fulfilling predetermined institutional requirements. At the same time it increases the in-country partner's awareness of private enterprise, academic and scientific research collaborator needs and characteristics
3. *Evaluating conservation requirements*: Varying objectives may require research in many different areas. Principle goals now include the development of conservation efforts and initiatives, so researching in-country capabilities should also cover ways to increase the value of natural resources and facilitate their conservation and sustainable utilization.

For INBio, understanding conservation requirements, together with the knowledge of markets and market players, is ensuring that INBio and Costa Rica will benefit as they should from collaborative agreements.

C. Technology access

Technology access, whether through development, transfer or acquisition, processes the raw materials of biological diversity into more valuable industrial inputs and products and promotes in-country capacity building.

- **Strong foundation of knowledge:** A preexisting base of taxonomic and traditional knowledge and scientific expertise (such as an inventory program) creates the initial base for attracting research collaborators and is the point of departure for increasing in-country knowledge and technologies.
- **Value-added:** Carrying out some level of in-country processing increases the value of simple raw materials by eliminating some steps of research counterpart processing. Traditional knowledge and preliminary screening accompanying samples also increase value, and have been argued to increase the ration of "hits" per sample group although the debate is on-going.
- **Capacity building:** Some level of processing is highly desirable to the in-country partner and is fundamental to linking research to national scientific and economic development. In-country processing improves national capabilities, creating a cycle in which continually advancing technological and scientific capacities attract more business partners and funding to be reinvested in further building those capacities.
- **Cost reduction:** Processing samples in the source country can be a cost-effective advantage for private industry if in-country processing is less expensive than the research partner's processing costs.

◆ **FINAL TOUCHES FOR THE FRAMEWORK: MULTI-SECTORAL COLLABORATIONS AND CONTRACT NEGOTIATION**

A. Multi-sectoral collaborations

Beyond these three elements, biodiversity prospecting activities must also seek to involve national and international entities. National collaborations will ensure that equitable returns make their way to support conservation efforts, academic, scientific and industrial development, and institutional objectives. International collaborations provide needed scientific and technological expertise as well as financial backing.

1. Principle actors include:

- the developing country government who acts as a gatekeeper, regulating access to biological resources and managing protected areas;
- the research collaborator which has the economic resources needed to finance the endeavor; and
- national and international academic and scientific communities whose expertise can contribute to increasing the relatively low market value of raw materials in-country.

2. INBio's principal national collaborations include:

- The INBio-Ministry of Natural Resources, Energy and Mines (MIRENEM) agreement that permits INBio to collect inventory and prospecting specimens and samples in the Costa Rican Conservation Areas. The agreement also provides the mechanism for returning benefits to protected areas.
- INBio-research and academic collaborations include agreements with the University of Costa Rica (UCR) and the Universidad Nacional (UNA) to jointly carry out preliminary sample research and processing.
- Collaborations with national institutions and private enterprise, such as the INBio-CORBANA and the INBio-Hacienda la Pacífica agreements will facilitate the development and production of a nematocide found in Costa Rica's dry forest (DMDP).

3. INBio's international collaborations include numerous research ventures with private enterprise: such as Merck & Co. , Eristol Myers Squibb, Givaudan-Roure, and the British Technology Group (BTG) among others; and with academic and scientific research centers: the National Cancer Institute (NCI), the National Institutes of Health (NIH), and Cornell University among others.

B. Contract negotiations

Once the components are carefully put into place and collaborators take their positions, it is essentially a question of negotiating research agreements to meet the requirements of the parties involved. The typical institutional and national needs INBio has focused on in negotiations include:

- √ generating income to support conservation areas and activities through direct contributions as well as royalties;
- √ providing a limited sample supply to ensure ecosystems and species remain undamaged;
- √ the transfer of processing technologies (equipment and know-how);
- √ creating opportunities for Costa Rican scientists;
- √ limited sample exclusivity to allow for broad sample-screening exposure; and
- √ guaranteed future profit sharing if commercial products are forthcoming.

Private, academic and scientific research partner needs and expectations generally include:

- √ access to new and diverse sources of biodiversity rich materials;
- √ a high level of assurance for resupply and adequate sample supply size;
- √ limited resource exclusivity;
- √ limited sharing of intellectual property rights;
- √ payment for resource commensurate with estimated/perceived market prices; and
- √ security of legal in-country practice for resource procurement.

◆ A CASE STUDY: THE INBIO-MERCK AGREEMENT

In 1991, INBio successfully negotiated these terms with the pharmaceutical giant Merck & Co. of New Jersey. Under the two-year agreement, Merck provided INBio with a US\$ 1 million research budget to jointly investigate a limited number of pre-selected plant, insect and soil samples for pharmaceutical research and development. INBio processes the samples into chemical extracts before being sent to Merck for screening and has agreed not to provide them to other companies for a two-year period while Merck studies them. All samples are well identified and documented, collected from the country's Conservation Areas in accordance with the INBio-MIRENEM collaborative agreement established in 1989.

The INBio-Merck agreement included donating a \$180,000, "state of the art" extraction facility to the University of Costa Rica's Chemistry Department and training four Costa Rican scientists both in Costa Rica and at Merck and other prestigious foreign research centers. Chemical extracts of collected samples are processed inside Costa Rica to continue advancing scientific capacities and build on the technologies accessed. Conservation also received significant direct benefits: ten percent of the research budget, a total of \$100,000, was donated to conservation efforts. The final element awarded INBio a percentage of royalties to be shared 50/50 with MIRENEM in the event of forthcoming products. The experience has been positive for both parties as the agreement's renewal in July, 1994 attests.

◆ EVALUATING THE SUCCESS OF BIODIVERSITY PROSPECTING AGREEMENTS

Measuring the success or failure of biodiversity prospecting agreements is more complicated than it appears. It is generally assumed that the sole objective of this new generation of prospecting agreements is to obtain an immense financial retribution (royalties) for natural resource conservation. Hence the news that marketable products will be costly, long in coming and may never even result leads many to brush aside the precedent setting nature of such agreements. At this juncture, however, we should be evaluating benefits beyond simple tangible monetary returns for conservation efforts and consider other visible elements such as equipment transfer and technology acquisition.

Success should also take into account *intangible* benefits including institutional development, capacity building, and national economic and industrial development, and those benefits that are more immediate. We must take into account the innovative nature of these agreements that expands beyond the preconceived notion that money alone will protect biological resources, and recognizes that conservation strategies must include short-term benefits to society to inspire their participation.

As an example, the INBio-Merck agreement can be assessed according to the following components:

A. Reversing traditions of inequitable retribution to the biodiversity rich source country:

- technology transferred to the UCR and INBio as laboratory equipment;
- scientific capabilities advanced through training opportunities (both institutional capabilities and national capacities were given attention);
- substantial monetary contribution to Costa Rica's protected lands paid directly and up front: \$152,000 awarded to the National Park Fund as of March 1995 (this sum will increase as the second agreement advances);
- conservation efforts, via the National Park Fund and MIRENEM, will receive 50% of INBio's royalties if products are forthcoming.

By small increments, these advances will attract more private industry interest and increase source country bargaining leverage because expertise equals a safer, professional agreement for companies.

B. Reorienting conventional values of biodiversity to foster attitudes favoring conservation and sustainable resource use.

- Including all sectors of society in prospecting activities whether through education or employment opportunities
- Covering institutional costs that promote biodiversity information management and dissemination.
- Advancing new, creative uses for biodiversity hopefully equally beneficial as traditional uses

◆ **THE BENEFITS OF MULTIPLE BIODIVERSITY PROSPECTING AGREEMENTS**

INBio enjoys other agreements with a variety of industries reflecting the conviction that one collaboration, or many of the same type of collaboration are unable to effectively fulfill all institutional goals and provide solutions to diverse national problems. Each biodiversity prospecting agreement is different, arising from a separate set of circumstances and responding to varying national, institutional and private enterprise needs.

A. DMDP, a phloem mobile nematocide

INBio is presently working in collaboration with numerous entities to develop a non-toxic pesticide, the, from a tree found in the country's northwestern dry forest and includes the following component:

1. *INBio-British Technology Group (BTG)-Kew Botanical Gardens*: chemical compound research and development, in addition to implementation of sustainable protocols for chemical extraction and raw material harvesting (with the initial support of the University of Costa Rica).
 - rights to exclusive research and commercial development for Costa Rica
2. *INBio-CORBANA*; Testing of the nematocide on bananas under tropical conditions in collaboration with the Costa Rican Association of Banana Growers (CORBANA). (Kew Botanical Gardens and BTG are responsible for testing the compound on potatoes and tomatoes)
3. *INBio-Hacienda la Pacífica*: Wild plant domestication in collaboration with Hacienda la Pacífica and the Guanacaste Conservation Area forestry station.
 - New employment opportunities for rural communities in the cultivation locale.

B. The Costa Rican International Cooperative Biodiversity Group (ICBG)

In a third agreement, the National Institute of Health (NIH), the National Science Foundation (NSF), Cornell University and Bristol Myers Squibb join INBio to form one of the world's five International Cooperative Biodiversity Groups (ICBG). The Costa Rican ICBG's objective is to:

- formally introduce insects into the pharmaceutical market, evolving new productive areas that other tropical countries might explore in the search for innovative conservation strategies that build national economies
- contribute to INBio's institutional development by providing funds to the Inventory and Information Management and Dissemination Programs as well as equipment for the Prospecting Program.

C. INBio-National Cancer Institute (NCI)

INBio and NCI are collaborating on the development of products for the treatment of cancer and the Human Immunodeficiency Virus (HIV).

- development of new screening procedures including the Bovine Immunodeficiency Virus (BIV) bioassay for detecting potential compounds useful for treating HIV.
- Collaboration in screening carried out with the University of Costa Rica.

D. INBio- UCR, INBio-UNA

Collaboration with major national universities and academic research centers is allowing Costa Rica to develop prospecting skills and a broader and clearer understanding of intellectual property rights on the national level through these agreements to develop guidelines for studying these fields in depth.

E. INBio-Givaudan-Roure

In INBio's latest collaborative agreement, the Institute will be exploring new sources of molecular combinations for fragrance development and marketing with Givaudan-Roure, a fragrance company. The agreement includes a research budget to cover sample collection and institutional costs; training of personnel in collecting and processing techniques; equipment transfer; portion of the research budget and 50% of royalties awarded to conservation; and two interesting new developments:

- completely sustainable collection methods; and
- arrangements include benefits conferred from rights of publication in magazine and television advertisements.

Each of these INBio agreements constitutes a learning experience in and of itself. Similarly, each of INBio's activities and projects mirrors this same experience, responding to and coping with a changing world and shifting perceptions of how best we might conserve valuable natural resources.

◆ **IMPROVING SOURCE COUNTRY CHANCES FOR SUCCESS**

Overall, we can conclude that the appearance of in-country biodiversity institutes, organizations and entities conducting prospecting activities and mediating between natural resources and developed country research partners are currently effective mechanisms for returning adequate benefits to the countries of origin. Secondly, we need to recognize that a large part of the control these entities exercise depends upon their systematic and scientific approach to collection and processing. In addition to information services such as traditional knowledge, careful collection processes offer strong possibilities to overcome the low probabilities of natural product discovery and development and confer added advantages for increasing bargaining leverage .

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INBio's National Biodiversity Inventory

elaborated for¹

"A Practical Workshop on Biodiversity Prospecting for
Cameroon, Madagascar and Ghana"

Santo Domingo de Heredia, Costa Rica
April 22 - May 3, 1995

Definition, Needs & Goals

The biodiversity inventory is an exercise that responds to the question of *what and where* biodiversity exists in Costa Rica. Before the foundation of INBio in 1989, information about Costa Rica's biodiversity was scattered among many diverse sources. To develop and coordinate national biodiversity information systematically, INBio's projected National Biodiversity Inventory will act as a "central library" for that knowledge. The Inventory will not simply "list" all the species in Costa Rica. Instead, the Inventory will ensure that every species is identified and represented by a specimen that has a name, a sample, a catalogue number, and a catalogue card containing fundamental taxonomic information ("what") and geographic information ("where"). Accordingly, the inventory will provide previously unavailable taxonomic information, a system for tracking contents, a system for making inventory loans, and a way of alerting users to available inventory services.

The inventory corresponds to the *knowledge* component of the "save-know-use" approach to biodiversity conservation. But the inventory does not seek knowledge for knowledge's sake alone. The primary goal of the Biodiversity Inventory is to enable Costa Ricans to use biodiversity in a manner that both (1) supports the conservation of biodiversity, and (2) creates opportunities for sustainable development within Costa Rica's broader economic and social context. In other words, the *use* of biodiversity will highly depend on the inventory -- the knowledge -- of Costa Rica's biological heritage. The Inventory will promote both social development and the protection of Costa Rica's Conservation Areas through creating the fundamental tool for integrating biodiversity with society, particularly local communities. INBio seeks a multi-participatory approach in these activities, looking for assistance from conservation, scientific, academic and commercial groups.

The National Inventory primarily takes place in Costa Rica's Conservation Areas, where parataxonomists collect and prepare

¹ This presentation has been adapted from the World Foundation for the Environment and Development project: *INBio Sourcebook* completed in July, 1994.

specimens. After identifying and cataloging the specimens at INBio headquarters, the biodiversity information feeds the database which will later facilitates the dissemination throughout society. The different users require data from the inventory for a wide range of resource management and conservation projects. In this manner, the Inventory benefits the people and biodiversity of the Conservation Areas. INBio estimates that the National Biodiversity Inventory will require \$30 million in funding over 10 years.

In support of its goals, the **specific objectives** of the biodiversity inventory include:

1. The creation of an authoritative systematically organized biodiversity reference collection for Costa Rica, which will serve as a solid taxonomic foundation for all work on the nation's biodiversity;
2. The integration, training, education, and involvement of local communities, particularly in and around the Conservation Areas;
3. The training of qualified and experienced personnel for inventory activities;
4. The efficient use, management, and conservation of resources, and;
5. The increased capacity for environmental monitoring.

The Biodiversity Inventory Parataxonomist Program

Every country faces a shortage of doctorate-level taxonomists to describe global biodiversity. To cope with this problem, INBio's Biodiversity Inventory has gone beyond the traditionally accepted methods of taxonomy. With approximately 5% of the planet's biodiversity, Costa Rica unfortunately has neither the time nor the resources to conduct an inventory according to the traditions of the scientific and academic community. Therefore, INBio has invested its taxonomic efforts directly in Costa Rica's Conservation Areas and local human resources through the parataxonomist program. The foundation of INBio's taxonomic process is the parataxonomist program, through which INBio employs local residents of different areas within Costa Rica.

Local parataxonomists have the added value of a lifetime's experience in the area's geography, climate, and social context. Parataxonomists are park guards and other lay persons mainly from rural areas with elementary to high-school education and a strong desire and motivation to accept a new intellectually challenging job. Some have prior experience as civil servants employed by the Ministry of Natural Resources who have been specifically assigned to this new task.

Parataxonomists work out of 20 "Biodiversity Offices" located across the country. The employment of local residents demonstrates one of the direct benefits of the conservation areas to rural communities. Beyond their role of collecting and preparing specimens, parataxonomists disseminate their knowledge and instill a value for biodiversity in their own communities and parks through educational programs geared to colleagues, neighbors, relatives, and local schools.

INBio promotes gender and ethnic equality in hiring parataxonomists. Once selected, INBio trains the future parataxonomists in a 6-month course. Training covers a wide range of subjects, including biology, ecology, and taxonomy. Parataxonomists also learn technologies such as trapping, preserving, and labeling of biological specimens, which are a fundamental part of their work. In the field, parataxonomists generally concentrate on the collection of specific taxonomic groups.

Challenges and Accomplishments in the Parataxonomist Program

INBio has confronted many challenges in establishing the parataxonomist program which have arisen both due to the innovative nature of the program, and because the parataxonomists come from a wide variety of social and economic conditions. INBio has successfully confronted challenges to the parataxonomist's program by providing constant feedback to the parataxonomists and being sensitive to their role in the social development of the country.

INBio's In-House Inventory Process

After a parataxonomist brings his or her collected specimens to INBio, different groups of technicians receive, sort, label, conduct basic taxonomic identification, and prepare the specimens for further identification. The technicians also enter, in a computer database, basic information on each specimen including identification of who collected the specimen and where it was found.

Curators further separate specimens to the lowest possible taxonomic level. They also ensure that the collection is accessible and organized. Curators typically have a B.Sc. degree in biology and a strong desire to work with a particular group of organisms. As with the parataxonomists and technicians, the tasks of the curators create new employment opportunities for Costa Ricans.

Finally, national and international taxonomy experts and specialists from local and foreign research centers work with INBio's curators and technicians on the description and identification of specimens at the species level. INBio works in a symbiotic relationship with visiting

scientists, who can bypass fieldwork for direct laboratory work with specimens (which minimizes their costs and time spent in the field), and INBio receives direct assistance in taxonomic identification of species. Furthermore, this type of partnership contributes directly to the development of the country's capacity to carry out this type of intellectual work using local resources. Some of the institutions that have collaborated with INBio include:

- The Natural History Museum (London)
- University of Pennsylvania
- Missouri Botanical Garden
- University of Minnesota
- The Smithsonian Institution
- Florida A&M University

During monthly visits to INBio's headquarters, INBio's in-house staff analyze and review the collected specimens with the parataxonomists. In 1994, parataxonomists collected a monthly mean of 42,440 insects. INBio's entomological collection includes over 2,319,366 specimens; the botanical collection includes over 19,500 specimens and the malacology collection includes 18,000 specimens.

Uses of the Biodiversity Inventory

The Biodiversity Inventory will provide **three primary types of information:**

1. **Scientific information**, including the specimen reference collection and the data of "what and where" species exist in Costa Rica;
2. **Institutional information**, including the knowledge about how to establish an inventory and appropriate administrative methodologies; and
3. **Educational information**, for example the parataxonomist outreach activities (*see* Information Dissemination - Educational Programs).

A large percentage of INBio's institutional work is based on information developed through the Inventory. For example, the Biodiversity Prospecting Division uses the Inventory for identification of potentially valuable species. The Information Management Program primarily works with information from the Inventory databases, formatting it for a variety of users. The Information Dissemination Program will not only act as the connection between the inventory and the

user, but will also use the Inventory data in its educational and promotional efforts.

Information Technologies

Once species are identified, the key to the utility of the inventory is making the information available and accessible to a wide range of users. Thus, information technologies are crucial in the inventory process. Information technologies include hardware equipment and software packages. The need for a sophisticated yet "user-friendly" information database has required the establishment of a Information Management Program, whose staff is developing the comprehensive Biodiversity Information Management System (BIMS) (*see* "Information Management Program").

Currently, the Biodiversity Inventory stores information on each insect sample using *4th Revolution* software for insects and *FoxPro* for plants. Once BIMS is completed, the information from each of these databases will be transferred to BIMS. INBio has also designed an innovative system in which each entomological specimen is given a bar-code label corresponding to a serial number as a rapid and efficient way to process and access information.

Biodiversity Information Management at INBio²

INBio staff is currently developing software systems to manage the available information on the Institute's National Inventory of Costa Rica (at present consisting of insect, plant and mollusk collections), as well as information pertaining to Biodiversity Prospecting projects.

1. Biodiversity Information Management System (BIMS)

BIMS is a specimen-based, integrated system composed of several modules. The basic one, the Inventory Module, captures and processes all inventory related information, such as lot number, taxonomy, specimen, and locality data. In the near future, BIMS will interact with a Geographic Information System (GIS) application. Spatial analysis, graphic reports etc. will then be available to the user. Some image processing will also be incorporated.

Equipment

INBio recently acquired a data server, a map file server, a digitizing table, ten UNIX workstations, a large-scale plotter and printers from the Intergraph Corporation of Huntsville Alabama. Intergraph also provided application development tools, networking software, and MGE, the modular GIS system.

² This section of the presentation was elaborated by Herbert Barrientos, in charge of BIMS development at INBio

System Description

In general the Inventory Module is divided into six components

1. Administrative sub-module: system definitions are set, user control is established and certain sensitive processes are executed.
2. Lot sub-module: captures information from specimen lots coming from the field. The data includes the date of specimen collection, the name and geographic information of the collection locality, elevation, a list of the participating collectors, habitat description, collecting methods, etc.
3. Specimen sub-module: keeps individual specimen information, namely the voucher number, preservation methods used, specimen type (organism, photograph, observation, etc.), collection to which specimen belongs (wet collection, dried and pinned, etc.), field notes and post annotations about the specimen, and a description of its components if it has been dissected for study.
4. Identification sub-module: gathers data entered by curators and other specialists about specimen identification. For each specimen, this information includes sex, life stage, date of identification, a list of identifiers and taxonomic classification. The taxonomic classification can be entered at the species level or any higher level, but only taxonomic levels above species can be updated. A history is kept on all identifications carried out on each specimen.
5. Taxonomy sub-module: manages taxonomic information of all kingdoms and comprises eighteen levels. Valid taxa and temporary names are handled by the Hierarchic Tree Structure. Other associated taxonomic information, also managed by this sub-module, are scientific and popular descriptions, taxon biology, taxon uses, authors, life forms, synonyms and common names.
6. Reports sub-module: among the various types of reports, this Inventory Module will have specimen, locality and taxonomic reports.

Other developments

Other applications, especially from the Biodiversity Prospecting Division will be interacting with BIMS through the local area network.

2. Publication of Biodiversity Information

Networking

A local area network connects the BIMS database with applications programmed for, and running on, UNIX equipment, Macintoshes, and

PC compatibles. A character-based interface will be developed for those external users interested in accessing the databases through Internet.

Printed Material

Data produced by the system will also be used to generate printed information such as field guides, brochures, slides, etc.

BIODIVERSITY PROSPECTING INFORMATION MANAGEMENT

Biodiversity Prospecting Program, Instituto Nacional de Biodiversidad (INBio),
April 20, 1995

Design and Interrelation of System Modules

A. General description:

Parallel to the steps followed for sample processing: collection, chemical processing, packaging and delivery, the Biodiversity Prospecting Program has developed an information system responding to multiple types of users. The Prospecting Information Management System's primary objective is to capture, organize information and generate reports regarding samples and also the laboratory process.

The system modules are organized as follows:

The **central nucleus of the process** (processing notebook) coordinates the traffic of samples between modules and facilitates the creation of executive reports permitting the samples to be monitored and given the appropriate follow-up from their collection in the field to the results of biological testing.

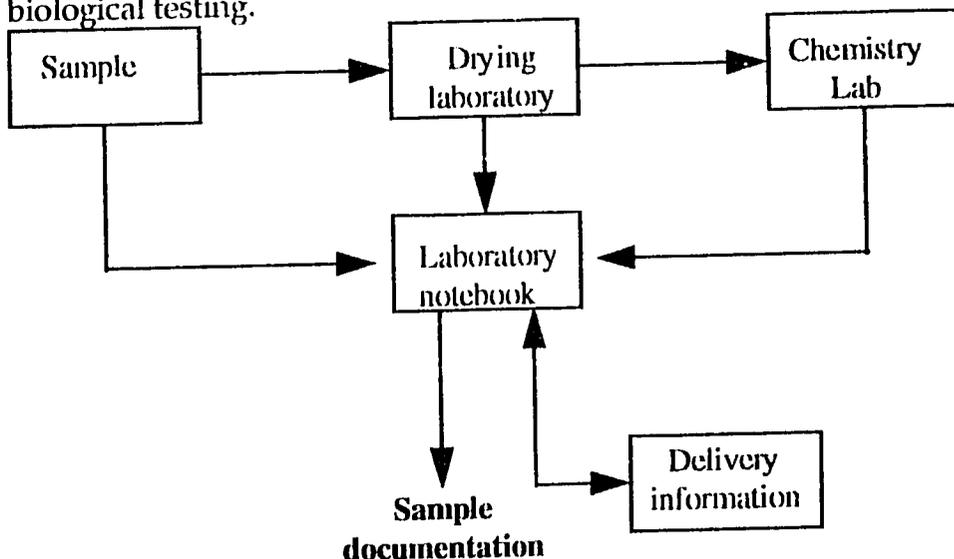


Diagram # 1: Using the laboratory notebook to construct a sample history

The **insect collection module** is divided into two parts:

I. A Filemaker (Macintosh) database exists for each eco-chemist who uses a PowerBook to manipulate important information in the field.

II. A central module developed in FoxPro for Windows which brings field information together and automatically assigns a code to the samples in order for them to arrive at INBio's laboratory for processing.

The **plant collection module** allows information brought in from the field by botanists to be organized.

The **drying module** is responsible for the wet extraction process during which the information generated is similar for both plant and insect samples. Given this, only one module is needed for both sample types.

The **chemical processing module** has been developed using FoxPro for Windows. The module automatically receives information concerning the samples to be processed from the central nucleus, and permits the information generated during the extraction process to be saved. The module varies depending on the protocols followed in the chemistry laboratory.

The final component, the **delivery control module** houses information relevant to delivery, including the delivery date for each sample, the package number, etc.

B. System design:

Structure of the principal database tables

An essential part of plant sample processing focuses on gathering collection data which is later introduced into the system, taking into consideration the following information:

- Sample code
- Project code
- Consecutive field collection code
- Date of collection
- Collecting site code
- Exact collection site
- Field expedition code
- Taxonomic identification code
- Level of taxonomic identification
- Comments

Because various parts (branches, leaves, roots) of a plant sample collected may be separated, a list of parts associated with the plant sample is required and includes the following information:

- Bar code
- Sample code
- Plant part
- Voucher
- Weight
- Sample condition (damaged, weight missing, in process etc.)

Information amassed in the field for insect samples is directly delivered to the system in electronic format with the following data included:

- Bar code
- Sample code
- Consecutive field collection code
- Life stage (egg, larva etc.)
- Collector
- Collection period
- Collection method (light trap, net etc.)
- Collecting site code
- Entomologist
- Sex (male, female, mixed)
- Method of preservation (frozen, alcohol etc.)
- Weight of insect
- Type of host (plant or other)
- Host voucher
- Taxonomic identification code for the host
- Level of taxonomic identification of host
- Date of delivery to INBio
- Project
- Comments
- Exact collection site
- Insect voucher
- Taxonomic identification code
- Level of taxonomic identification

This information is processed and verified in INBio before it is introduced into the collection database.

If the project protocol requires the sample to undergo wet extraction preceding the chemical processing, then, in addition to the collection information gathered, the samples are labeled with respective bar codes and sent through the drying process. The following information is obtained for drying:

- Bar code
- Sample code
- Type of sample
- Date of delivery to INBio
- Date of delivery to INBio
- Dry weight
- Type of grinding
- Ground weight
- Date of process termination
- Hour of process termination

- Hour of delivery to INBio
- Initial presentation (frozen, alcohol etc.)
- Weight
- Type of drying
- Weight of material to be dried
- Weight delivered
- Number of bags
- Destination
- Comments

Whether or not the material requires drying or not, the samples are next delivered to the chemistry laboratory where the following information is registered:

- Bar code
- Sample code
- Consecutive laboratory notebook code
- Weight for processing
- Number of bags or bottles
- Date of laboratory arrival
- Protocol
- Weight for extraction
- Comments

As various bottles are obtained from each sample depending on the solvents used, the following information must be stored for each bottle:

- Bar code
- Sample code
- Solvent
- Extract weight
- Bottle weight
- Bottle number
- Date of extraction
- Stage (process, damaged etc.)

Diagrams one and two respectively correspond to the flow of data between the principal entities of the process and the database's entity-relation diagram.

C. Equipment:

INBio's Biodiversity Prospecting Program is equipped with six IBM-compatible computers, 5 portable Macintosh PowerBooks for use in the field, one Macintosh Classic II, various printers (of which one is used for printing bar codes) and a bar code reader.

The IBM-compatible computers are linked to the INBio's PC network by Banyan VINES, making the network's hard drive and other resources such as Internet available to users. The entire information system operates using this equipment which is located at different work stations in the laboratories involved in the process.

D. Conclusions:

To the present date, the Prospecting Program has achieved a high level of success in designing and implementing systems for managing relevant information principally because the system has evolved along with the process itself. Although there remains much to cover still, the Prospecting Information Management Program's central objective is integrating all of the data nuclei in such a way that INBio's different departments (Inventory, Prospecting, Information Management, and Information Dissemination) can be freed from satoring and processing redundant information.

In order to do this, we will need to develop and/or access:

- Available technology, both hardware and software
- Tools necessary to develop the different systems that take into account the volumes of data being managed, appropriate security , etc.
- Develop applications using these tools that are advanced yet simple enough to be used by diverse individuals who are not experts in information management.

DRYING SAMPLES FOR CHEMICAL PROCESSING

Biodiversity Prospecting Program, Instituto Nacional de Biodiversidad (INBio)
April 20, 1995

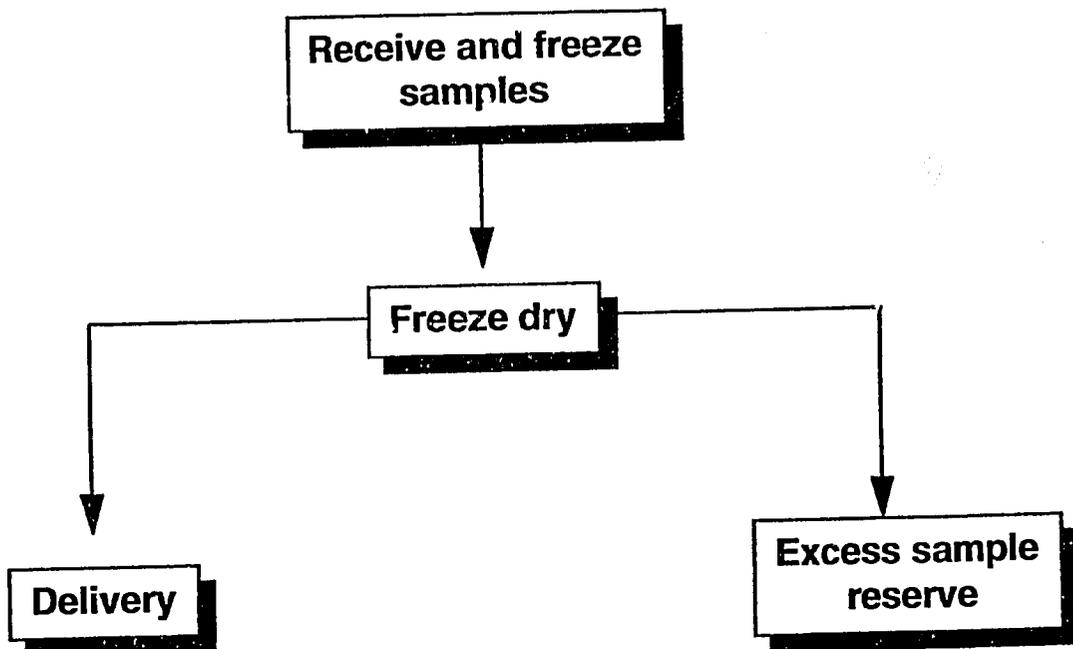
PLANTS:

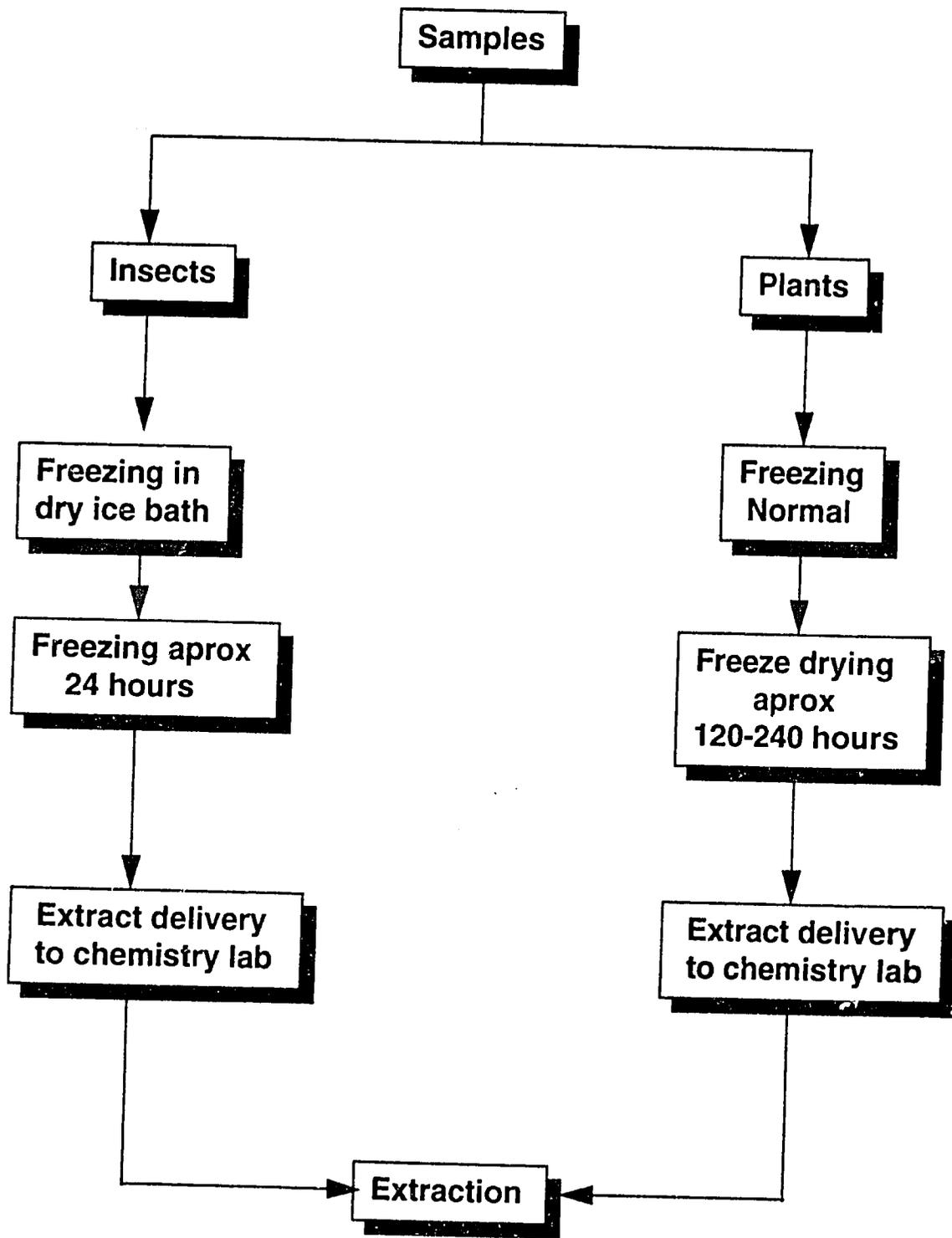
1. Plant material is received from the field in large plastic bags accompanied by a label and delivery formula.
2. Once in INBio the samples are divided into smaller packages using various cutting tools (machete, ax, scissors etc.).
3. The smaller packages are then frozen for 24 hours.
4. Following this, the samples are freeze dried, a process that takes an average of 160 to 240 hours. All data regarding the sample at this point must be noted for control sample.
5. The freeze dried material is ground and carefully packed to avoid confusing samples. The total dry weight is taken down in the record book and the database in order to create the corresponding labels and delivery formulas.
6. The material is delivered to the chemical extraction laboratory.

INSECTS:

1. Insect samples are received from the field frozen and accompanied by a label and delivery formula.
2. The insects are placed in bottles and frozen in a dry ice/acetone bath before the freeze drying process. All details and data regarding this process must be taken down in the laboratory record book.
3. The freeze drying process then takes an average of 24 hours.
4. The freeze dried insects are transferred to other previously weighed bottles and the dry weights are noted in the record book. The data is then entered into the database in order to obtain the corresponding labels and delivery formulas placed in the respective bottles.
5. The insects are finally delivered to the chemical extraction laboratory.

Drying and Grinding



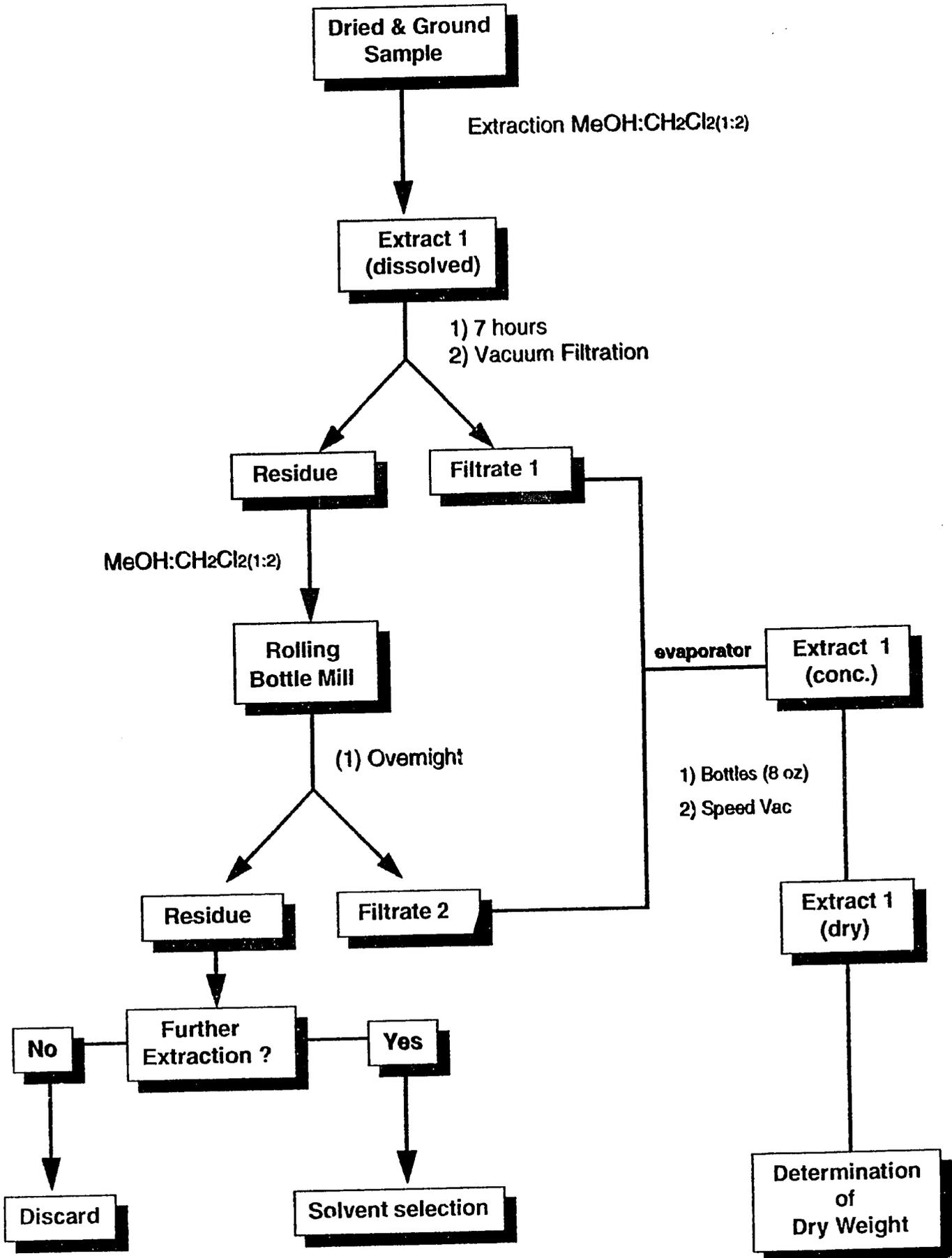


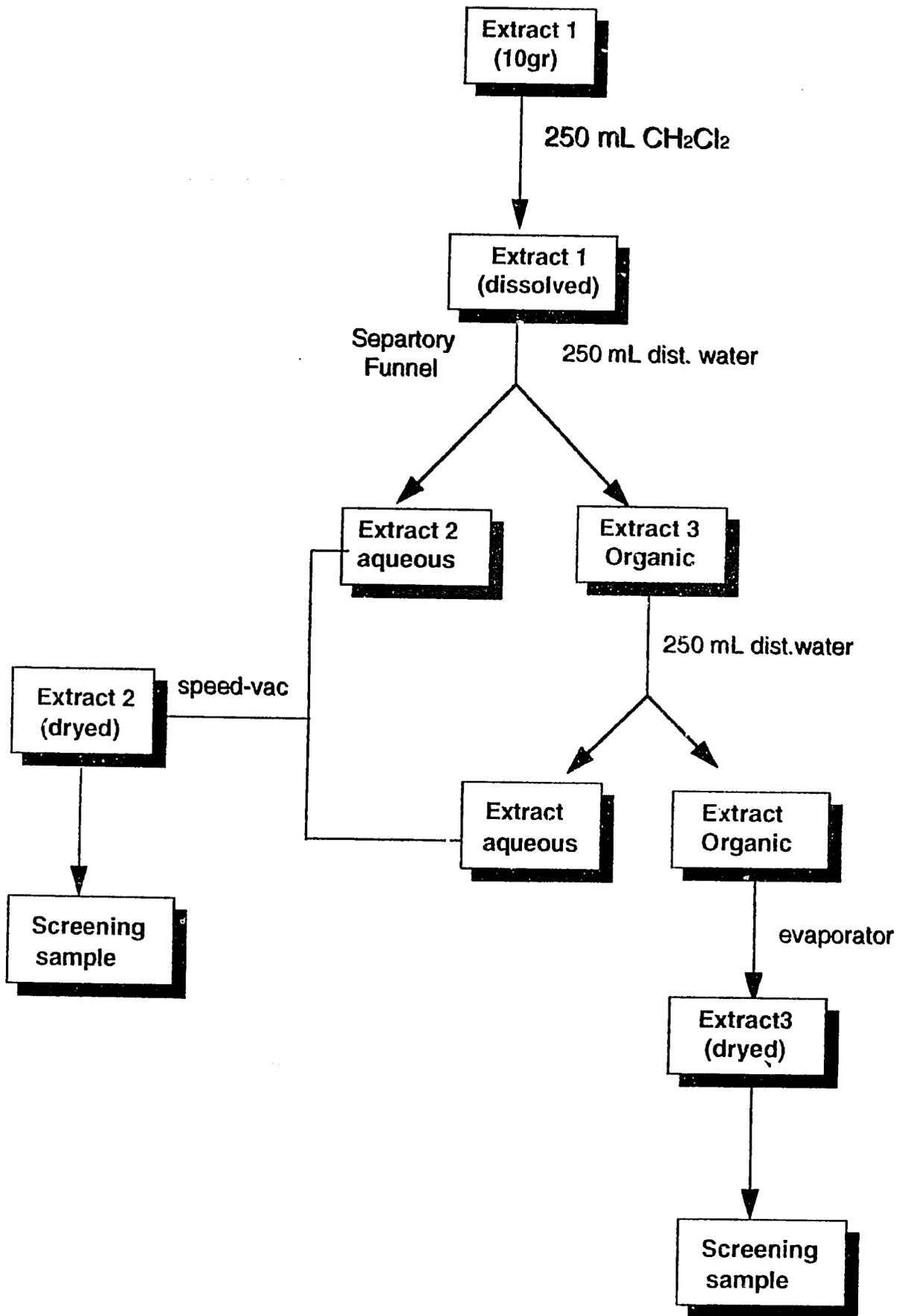
CHEMICAL EXTRACTION OF PLANTS

Biodiversity Prospecting Program, Instituto Nacional de Biodiversidad (INBio),
April 20, 1995

1. The laboratory receives plant samples (dried and ground) accompanied by their corresponding delivery formulas specifying the code number and dry weight of each sample.
2. A laboratory number is then assigned to each sample and the weights verified.
3. Data such as the code, the laboratory number, total dry weight and date of extraction are noted in a registry to record samples that will be processed in the lab.
4. Each sample is placed in an appropriate bottle using an adapter funnel.
5. The bottles are filled with a mixture of dichloromethane:methanol (2:1).
6. The bottles are then sealed with Teflon caps and are placed in a rolling bottle mill.
7. After a period of eight hours in the mill, the samples are filtered off to separate soluble compounds (raw extraction # 1).
8. Once again the same solvents are added to the bottles for a second extraction that lasts overnight (raw extraction #2).
9. Afterwards, the samples are filtered and then concentrated by rotary evaporation. The concentrated samples are transferred to 8oz. bottles and dried by means of a Speed-Vac equipment.
10. The weight of the dried samples is then determined, 10 grams of this dissolved in 250 ml of dichloromethane, and then partitioned twice with 250 ml distilled water.
11. The organic layer is washed with 50 ml distilled water and the aqueous layers combined.

12. The organic layer is then concentrated and transferred to a 40 ml vial where it is finally dried.
13. The aqueous extract is freeze dry.
14. The weight is documented for each dried extract and screening samples are prepared to determine biological activities : 10 mg for Phospholipases A2, 10 mg for antimicrobial activity and 100 mg for "in vivo" Malaria screening.





INSECT EXTRACTION PROTOCOL

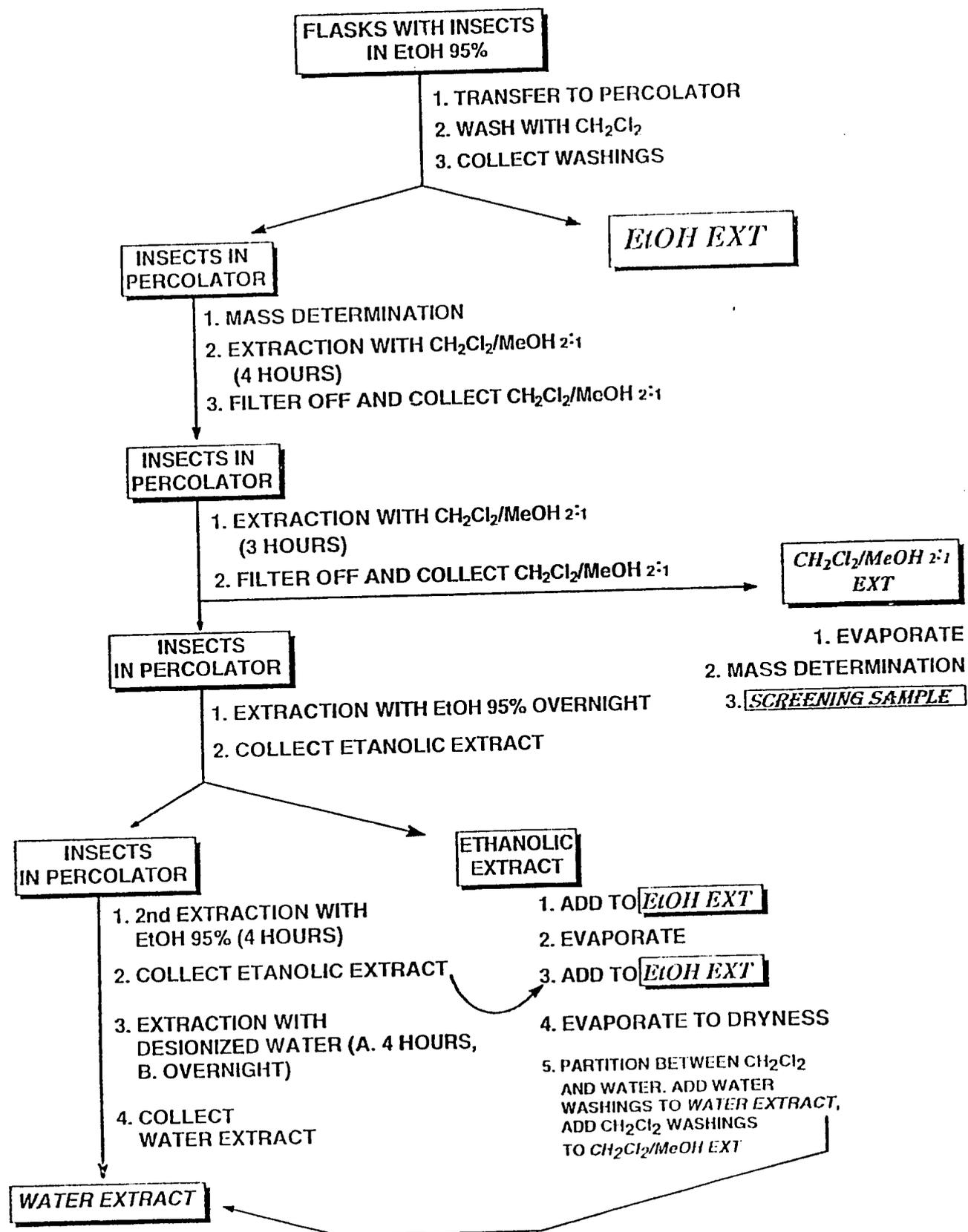
Biodiversity Prospecting Program, Instituto Nacional de Biodiversidad (INBio),
April 20, 1995

1. In the field, insect specimens are collected, bottled in jars and preserved in ethanol. Samples are then received in INBio, accompanied by a field code. They are assigned a laboratory code ("INBio code") which are listed in memorandums.
2. The laboratory code assigned to each jar is a consecutive number.
3. Once at INBio, the first step is to log the entry of specimens into a laboratory notebook. The entry includes the date of processing, the INBio code, insect characteristics and the fresh weight of a given sample.
4. The fresh weight is determined by filtering off the ethanol ("external ethanol") in which the insects have been preserved using a percolator. An initial drying of the specimens is carried out using a small quantity of CH_2Cl_2 and from there they are placed into a previously tared beaker and the total weight determined. A mixture of $\text{CH}_2\text{Cl}_2/\text{MeOH}$ with a proportion of 2:1 is added to the beaker and the contents are ground with a hand blender. A magnetic stir bar is placed in the beaker and the whole is left to mix over a period of four hours.
5. The mixture is then filtered through the percolator and a second extraction is carried out using $\text{CH}_2\text{Cl}_2/\text{MeOH}$ 2:1 for three hours. After this time period, the contents are filtered once again.
6. Immediately following, a first extraction using a 95% ethanol solution is carried out overnight. The next morning, the ethanol ("external ethanol") is filtered out and added to the first filtration of ethanol that took place in step 4. A new extraction using 95% ethanol solution is then carried out over a period of four hours. Afterwards, the contents are filtered and extracted with water: first for four hours and then a second time overnight.
7. The ethanol extracts are evaporated to dryness, and once thoroughly dried, they are partitioned with CH_2Cl_2 and water. Both fractions are collected in separate vessels.
8. All dichloromethanol/methanol extracts, including the outcome of step 5, are mixed together and concentrated in the rotavaporizers. In

concentrated form the contents are placed in vials previously weighed. The fractions are further evaporated using nitrogen or in a fume hood.

9. Aqueous fractions and the extract obtained in step 6 are mixed together and the remainder of the organic solvent, ethanol, is evaporated.
10. Once the solvents have been evaporated and freeze dried, the weight of the raw extract is determined and the whole transferred to vials for screening samples of 10 mg (Phospholipase A₂ inhibition), 100 mg (Malaria), or 10 mg for antimicrobial analysis in the microbiology laboratory at INBio.
11. All of the data obtained, including different weights and observations made throughout the extraction processes are fully documented in the department database.

INSECTS EXTRACTION PROTOCOL



1. DRY UP
2. WEIGHT DETERMINATION
3. SCREENING SAMPLE

MICROBIOLOGY LABORATORY

Biodiversity Prospecting Program, Instituto Nacional de Biodiversidad (INBio),
April 20, 1995

I. Introduction

A. Functions

The first phase of the Microbiology Laboratory of the Biodiversity Prospecting Program is dedicated to investigate new biomaterials as source for drug discovery. Extracts from plants, arthropods and mollusks are currently being tested for antifungal and antibacterial activity.

B. Financial support

The laboratory was established as a part of the Costa Rican International Cooperative Biodiversity Group project (ICBG).

C. Description of the laboratory

The laboratory measures 15 m² with the minimal necessary equipment for general microbiological work. It contains: a laminar flow bench, incubators, a shaker incubator, a microscope, a colony counter, etc.

D. Relationships with laboratories from other institutions

Collaborations have been established with: the Faculty of Microbiology, at the University of Costa Rica (UCR), the Center for Research in Cell and Molecular Biology (CIBCM), and the Chemistry School (UCR).

II. Culture of fungi and bacteria: storage of the strains

The strains are maintained at -70°C at the Faculty of Microbiology and the CIBCM. At INBio, the strains are kept at -20°C and 4°C. The fungi are cultured in Sabouraud Agar and the bacteria in Trypticase Soy Agar and other media according to nutritional and the varying needs of different microorganisms.

INBio's Collection for bioscreening includes several strains of:

Saccharomyces cerevisiae, *Candida albicans*,
Escherichia coli, *Staphylococcus aureus*,
Klebsiella pneumoniae, *Pseudomonas aeruginosa*,
Bacillus subtilis.

III. Techniques for determining antimicrobial activity

The techniques utilized are simple and adaptable to any laboratory with the minimal equipment, including laboratories in biological stations.

EXTRACTION OF BIOACTIVE MOLECULES FROM PLANTS

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Introduction

The NCI/DTP anticancer/antiviral screening effort at the Frederick Cancer Research and Development Center requires the processing of 4,000 higher plant specimens each year for 5 years. Of primary concern was the development of processing protocols that maximize the probability of extracting biologically active molecules from the specimens, and of preserving that activity through the processing and storage of extracts. During the methods development phase of the project all aspects of processing were evaluated:

Storage of specimens

Grinding operations

Solvent extractions

Extract drying

Extract storage

Grinding Operations

Air dried plant specimens were ground in either a Wiley (knife) mill, or a hammer mill. Large stems or roots were first cut with a bandsaw. Grinding to a very fine powder would require more time, and expose the specimen to heating, yet improve speed of extraction. Coarse grinding requires less mill time and minimizes exposure to heat, but lengthens time required for complete extraction. A compromise was desired which allowed rapid grinding and high throughput with a minimum of heating, but gave a particle size with acceptable flow properties and efficient extraction by solvent in a percolator.

Various plant parts were ground in the two different mills using different screen sizes. The following table shows examples of the particle size distributions obtained when a 10 mm screen is used in a hammer mill and a 5 mm screen is used in a Wiley mill.

Plant part	Particle Size Distribution (percent)					
	>2.8 mm	1-2.8 mm	0.5-1 mm	0.18-0.5 mm	<0.18 mm	
lf/st	11	57	21	7	2	Hammer mill (10 mm screen)
rt	12	38	24	14	9	
bk	44	30	13	6	4	
bk	24	39	20	10	6	
wd	28	37	15	14	6	
wd	33	45	14	5	2	
wd	38	46	8	5	2	
wd	50	30	9	7	3	
fr	43	20	16	12	8	
fr	30	37	17	12	5	
lf	0	12	10	33	45	Wiley mill (5 mm screen)
pl	0	36	36	18	8	
pl	4	40	28	20	8	
lf	8	53	18	9	9	
lf	1	50	36	10	2	
lf	3	58	23	10	6	
lf/st	1	26	45	20	8	
lf/st	1	26	42	21	9	
fr	2	71	16	8	2	
fr	2	75	17	6	1	

Comment:

1. When fibrous plant parts are hammer milled, many "cottony" particles are produced which do not pass through a 2.8 mm mesh sieve. Since the structure of the plant has been thoroughly disrupted, solvent penetration of these particles is very good, so solvent extraction is effective.

2. Samples are ground directly into the bottles used to store the specimen until extracted.

3. The data presented is for air-dried plant specimens which normally contain about 10% moisture. Oven-dried or lyophilized plant specimens were observed to give a significantly greater percentage of very small particles.

4. Mesh sizes of 10 mm for a hammer mill and 5 mm for a Wiley mill give high throughput of ground plant material while minimizing heating, and produce particles with a size distribution which gives good extractability and flow properties in the percolator.

5. The grinding mills are thoroughly cleaned (vacuum cleaner, compressed air, solvent-moistened cloth towel) between the grinding of each specimen.

Extraction Methods

1. The Extraction Vessel

To gain the advantage of a semicontinuous flow-through system, borosilicate columns 10 cm in diameter and of various lengths were fitted with a Teflon vacuum-type stopcock. The heavy-walled glass with a flange at the top is very space-efficient since it can be hung from a single support, allowing 12 percolators to be placed inside a single 6 ft California hood. The specimen comes into contact with only borosilicate glass and Teflon. A vacuum adapter on the stem allows solvent to be quickly drained from the percolator into the round bottom flask used for rotary evaporation.

2. The Solvents Used for Extraction

The extraction efficiency of various solvents, solvent mixtures, and sequences has been tested. Plants known to contain biologically active substances varying widely in chemical type were selected. Each extract was processed in a consistent manner (i.e., length of time for extraction, temperature during solvent removal, drying) and biological evaluation was done to demonstrate that the active substance had been extracted. Failure to extract or degradation of an active substance would result in rejection of a method. Completeness of extraction, as measured by mass yield, was a consideration only secondary to activity. The tables give some examples of the extractions performed:

3. Extraction Protocol: Time and Multiplicity Considerations

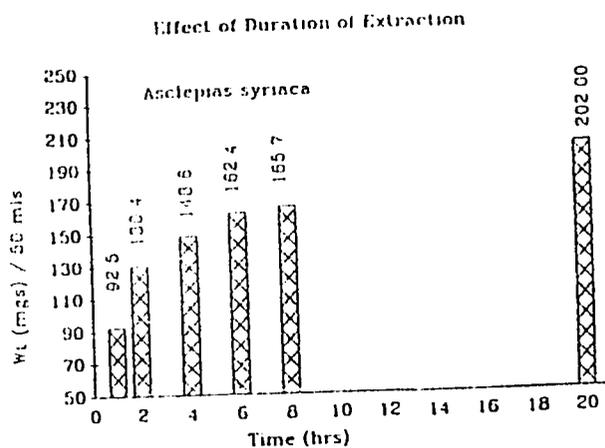
To determine the speed at which the solubles within a ground specimen are partitioned into the solvent of choice, a single plant sample was allowed to steep in solvent. Aliquots of solvent were removed at intervals, dried, and weighed. Figure A shows that the maximum concentration of extractables is approached slowly up to about 20 hrs.

Figure B shows that a single, overnight percolation in methylene chloride/methanol (1:1) allows removal of approximately 80% of the total organic solvent extractables.

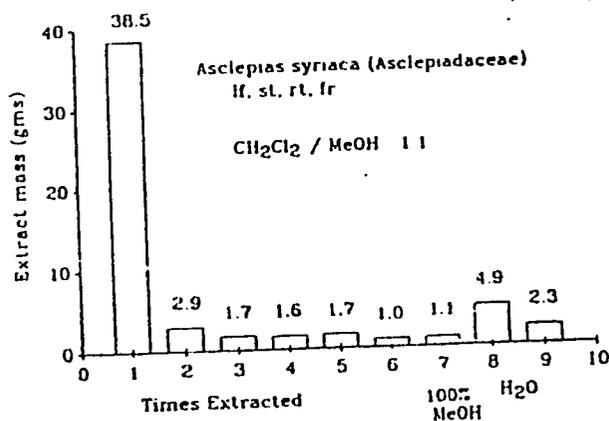
Comment:

1. No solvent(s) were found which demonstrably destroyed a known biologically active compound.
2. An initial extraction with organic solvent followed in sequence with water, or the reverse, made no difference in the detectability of known active compounds.
3. The efficiency of extraction as measured by mass can vary considerably with solvent.
4. An overnight steeping in methylene chloride/methanol (1:1), followed by a brief wash in 100% methanol (combined to give a single organic extract), was the most effective extraction method found. A second extraction of the marc (which contains 8 to 12% methanol) with water efficiently removes the more polar constituents.
5. Organic extracts are always dried the same day. Aqueous extracts are immediately frozen and later lyophilized.

A

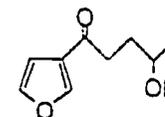
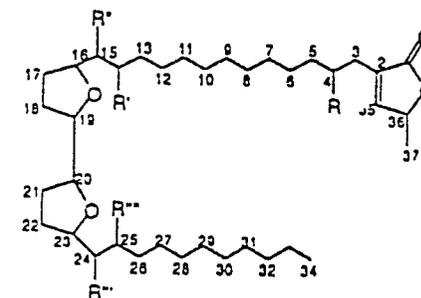


B



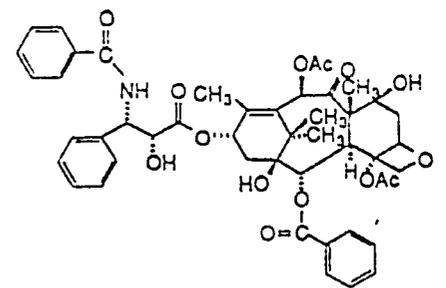
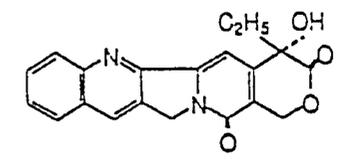
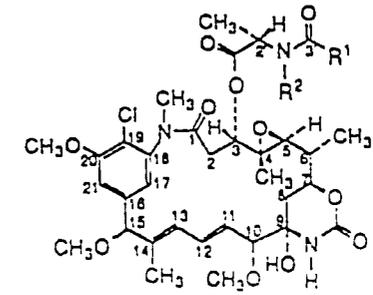
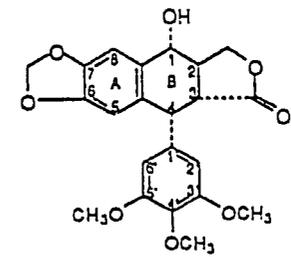
	EtOH	MeOH	MeOH/ Toluene	MeOH/ CH ₂ Cl ₂ 1:1	*MeOH rinse	*Aq re-extract	H ₂ O/ MeOH 9:1	*MeOH/CH ₂ Cl ₂ re-extract	H ₂ O
Brassica oleracea var. capitata "Flathead cabbage"									
Cruciferae									
Percent extractables	27.0	29.5	31.9	36.7		5.2	39.6	4.1	
BSL (mg/ml)	0.2	>1	0.3	0.4		>1	>1	>1	
P388 (in vitro)	>100	>100	>100	45		>100	>100	>100	
A549 Asc - 1 (Lung)	>383	>415	>408	>398		>336	>398	>360	
HT29 (Colon)	>383	>415	>408	>398		>336	>398	>360	
SNB - 19 (CNS)	>383	>415	>408	>398		>336	>398	>360	
UO - 31 (Renal)	>383	>415	>408	>398		>336	>398	>360	
Asimina triloba Ws,Sb,Tw,Lf									
Annonaceae									
Percent extractables	1.7	2.6	2.4	4.2		2.7	2.4	1.8	3.3
BSL (mg/ml)	0.01	0.01	0.08	0.02		1.0	0.28	0.02	0.24
P388 (in vitro)	0.26	0.46	0.48	1.8					
A549 Asc - 1 (Lung)	<0.24	<0.76	<0.67	<0.76		>362	7.6	<0.9	39
HT29 (Colon)	<0.24	<0.76	<0.67	<0.76		>362	182	<0.9	61
SNB - 19 (CNS)	<0.24	<0.76	1.1	0.8		>362	58	<0.9	38
UO - 31 (Renal)	56	62	0.8	4.5		>362	29	16	19
Ipomoea batatas Tubers									
Convolvulaceae									
Percent extractables	9.6	16.3	11.5	10.5					
BSL (mg/ml)	0.32	>1	>1	>1					
P388 (in vitro)						0.87			
A549 Asc - 1 (Lung)	141	190	147	>322		>353			
HT29 (Colon)	209	236	227	>322		>353			
SNB - 19 (CNS)	95	75	35	>322		>353			
UO - 31 (Renal)	150	199	150	>322		169			

Presumed Non-cytotoxic Control

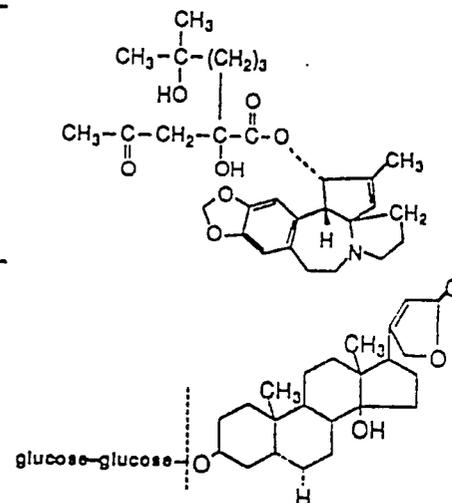


120

	EtOH	MeOH	MeOH/ Toluene	MeOH/ CH ₂ Cl ₂ 1:1	*MeOH rinse	*Aq re-extract	H ₂ O/ MeOH 9:1	*MeOH/CH ₂ Cl ₂ re-extract	H ₂ O
<i>Podophyllum peltatum</i>	Rt "May apple"								
Barberidaceae									
Percent extractables	7.6	10.3	9.3	9.5		7.5	13.4	5.8	16.8
BSL (mg/ml)	0.0036	0.0047	0.0033	0.0037		0.05	0.013	<0.01	<0.01
P388 (in vitro)	0.02	0.04	0.03	0.03		0.37	0.04	0.01	
A549 Asc - 1 (Lung)	<0.03	<0.03	<0.03	<0.03		0.22	0.09	<0.03	0.07
HT29 (Colon)	<0.03	<0.03	<0.03	<0.03		0.66	0.21	<0.03	0.19
SNB - 19 (CNS)	<0.03	<0.03	<0.03	<0.03		0.21	0.08	<0.03	0.07
UO - 31 (Renal)	<0.03	<0.03	<0.03	<0.03		0.23	0.09	<0.03	0.09
<i>Taxia nudiflora</i>	Sd								
Euphorbiaceae									
Percent extractables	7.6	10.3	9.3	9.5		7.5	13.4	5.8	16.8
BSL (mg/ml)	0.0036	0.0047	0.0033	0.0037		0.05	0.013	<0.01	<0.01
P388 (in vitro)	0.02	0.04	0.03	0.03		0.37	0.04	0.01	
A549 Asc - 1 (Lung)	<0.03	<0.03	<0.03	<0.03		0.22	0.09	<0.03	0.07
HT29 (Colon)	<0.03	<0.03	<0.03	<0.03		0.66	0.21	<0.03	0.19
SNB - 19 (CNS)	<0.03	<0.03	<0.03	<0.03		0.21	0.08	<0.03	0.07
UO - 31 (Renal)	<0.03	<0.03	<0.03	<0.03		0.23	0.09	<0.03	0.09
<i>Camptotheca acuminata</i>	Rt								
Nyssaceae									
Percent extractables	3.1	2.4	3.6	6.5	1.2	3.5	5.1	4.7	3.8
BSL (mg/ml)	0.08	0.03	0.05	0.08	0.03	0.29	0.16	0.14	0.11
P388 (in vitro)	0.07	0.04	0.04	0.5	0.4	0.8	0.6	0.4	0.7
A549 Asc - 1 (Lung)	<.03	<.49	<.98	<.06	<.98	1.9	1.0	<.49	<.98
HT29 (Colon)	<.03	<.49	<.98	<.06	<.98	1.5	<.98	<.49	<.98
SNB - 19 (CNS)	<.03	<.49	<.98	<.06	<.98	<.98	<.98	<.49	<.98
UO - 31 (Renal)	0.41	<.49	<.98	1.24	<.98	13	12	<.49	1.9
<i>Taxus brevifolia</i>	Bk (female)								
Taxaceae									
Percent extractables	0.8	4.4	4.7	3.0		3.0	8.6	2.1	7.2
BSL (mg/ml)	0.2	0.12	0.08	0.026		>1	0.59	0.06	>1
P388 (in vitro)	5.5	4.0	2.8	3.1		39	32	2.8	45
A549 Asc - 1 (Lung)	<2.81	<0.67	<2.83	<0.25		<2.6	4.3	<0.9	3.7
HT29 (Colon)	<2.81	<0.67	<2.83	<0.25		27	37	<0.9	30.3
SNB - 19 (CNS)	<2.81	<0.67	<2.83	<0.25		8.8	13	<0.9	16
UO - 31 (Renal)	<2.81	<0.67	<2.83	<0.25		<2.6	4.3	<0.9	3.6



	EtOH	MeOH	MeOH/ Toluene	MeOH/ CH ₂ Cl ₂ 1:1	*MeOH rinse	*Aq re-extract	H ₂ O/ MeOH 9:1	*MeOH/CH ₂ Cl ₂ re-extract	H ₂ O
<i>Cephalotaxus harringtonii</i> Sb									
Cephalotaxaceae									
Percent extractables	4.5	7.1	6.3	3.9	4.0	5.9	8.8	1.4	4.7
BSL (mg/ml)	0.37	0.28	0.68	0.12	0.43	0.77	0.45	0.10	
P388 (in vitro)	37	35	15	45	45	80	>100	42	>100
A549 Asc - 1 (Lung)	>62.5	>125	37	>62.5	>62.5	>125	>125	>125	>125
HT29 (Colon)	>62.5	>125	28	>62.5	>62.5	>125	>125	>125	>125
SNB - 19 (CNS)	>62.5	>125	20	>62.5	>62.5	>125	>125	>125	>125
UO - 31 (Renal)	>62.5	>125	>125	>62.5	>62.5	>125	28	>125	21
<i>Asclepias syriaca</i> St, Lf, Sd "Common milkweed"									
Asclepiadaceae									
Percent extractables	3.3	3.1	3.5	3.8	1.4	3.0	4.1	4.0	4.5
BSL (mg/ml)	>1	>1	>1	>1	>1	>1	0.59	1.03	
P388 (in vitro)	42	>100	>100	>100	>100	>100	>100	40	>100
A549 Asc - 1 (Lung)	>31.3	>31.3	>62.5	>62.5	22.1	>125	>125	>31.3	49
HT29 (Colon)	>31.3	>31.3	>62.5	>62.5	>31.3	>125	>125	>31.3	>125
SNB - 19 (CNS)	>31.3	>31.3	>62.5	>62.5	>31.3	>125	>125	>31.3	>125
UO - 31 (Renal)	>31.3	>31.3	>62.5	>62.5	>31.3	>125	>125	>31.3	89
<i>Castanea dentata</i> Tw, Lf, bk "American chestnut"									
Fagaceae									
Percent extractables	0.7	2.6	2.9	2.4	1.1	1.9	2.6	2.8	1.1
BSL (mg/ml)	>1	>1	>1	>1	>1	>1	>1	>1	>1
P388 (in vitro)	43	30	40	33	30	>100	>100	27	>100
A549 Asc - 1 (Lung)	30	>125	>125	36		>125	>125	44	87
HT29 (Colon)	>31.3	>125	>125	37		>125	>125	47	>125
SNB - 19 (CNS)	>31.3	>125	96	16		31	27	18	76
UO - 31 (Renal)	0.3	3.0	>125	35		26	39	33	85



Tanins & Polyphenolics

Conclusions and Protocol

The following protocol has been adopted for processing plant specimens in the NCI/DTP screening effort at the Frederick Cancer Research and Development Center:

1. All specimens, whether whole or ground, are stored at -20°C unless undergoing processing.
2. All specimens are ground to a powder for extraction.
3. Ground specimens are solvent extracted in the following way:
 - a. Overnight steeping at room temperature covered by a 1:1 mixture of methylene chloride/methanol.
 - b. After draining the solvent, the marc is covered with 100% methanol for about 15 minutes, then this is drained into the same flask to give a combined organic solvent extractables fraction.
 - c. Solvent is removed by rotary evaporation with a water bath temperature not exceeding 40°C .
 - d. The concentrate is transferred to a borosilicate glass bottle and the residual solvent removed. A final drying takes place at a 100 micron vacuum. The solvent removal and final drying occurs within 24 hrs. of extraction. A bottle cap with Teflon liner is tightened and sealed with a spot of hot-melt glue. This bottle is kept at -20°C until needed for testing or fractionation.
 - e. The marc is covered with high purity water and allowed to steep overnight at room temperature. The aqueous extract is drained and immediately frozen in a borosilicate dish. After lyophilization, the dry material is transferred to a borosilicate storage bottle and stored as above.
4. In keeping with the collection permit, all contaminated materials, dust, plant bags, contents of vacuum cleaners, plant marcs, etc. are incinerated at the center.

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SECTION 5

BUSINESS DEVELOPMENT STRATEGIES: DESIGNING EQUITY INTO BIOPROSPECTING AGREEMENTS

SECTION 5: BUSINESS DEVELOPMENT STRATEGIES: DESIGNING EQUITY INTO BIOPROSPECTING AGREEMENTS

Introduction:

It is not enough to simply collect and identify genetic resources, prepare extracts and run biological assays in the attempt to isolate biologically-useful molecules. Equitable bioprospecting implies that some mechanism exists to return the benefits of this research and development to local communities in some manner that both enhances social welfare and creates incentives for conservation.

Developing a feel for the actual market for genetic resources and acquiring the contacts and skills to negotiate an equitable business agreement with a private sector partner is necessary to derive any benefit from the economic development of genetic resources. The first paper by Daniel Putterman outlines the current market for genetic resources as well as the process of pharmaceutical research and development. Marketing strategies are also briefly presented.

Part 5 of the first paper briefly sketches strategies for designing equity into bioprospecting contracts. An overview of Bioresources Development and Conservation Programme (BDCP) of Cameroon and Nigeria expands upon this theme of community development. BDCP aims to create conservation programs which link the developmental needs of people living in tropical countries with protection of the environment. A non-governmental and non-profit international organization, BDCP brings together a collaborative group of natural products scientists, environmentalists and industrialists. Its current director, Dr. Maurice Iwu, is a medicinal chemist and traditional healer whose research program includes investigating traditional uses of African medicinal plants. BDCP supports the development of low-cost phytomedicines accessible to a wide cross-section of developing-country populations, and also works to promote the development of ethical pharmaceuticals.

The final document presented in this section is a policy document from Glaxo Research and Development illustrating how large multinational corporations can encourage responsibility in the acquisition of genetic resources from biodiversity-rich nations.

Contents: Section 5

- An Overview of the World Market for Genetic Resources: Marketing Value-Added Products in a Competitive World. By Daniel M. Putterman
- Finding the Link Between Conservation and Development. Mission Statement of Bioresources and Development and Conservation Programme of Nigeria and Cameroon
- Policy for the Acquisition of Natural Product Source Samples. By Glaxo Research and Development (reprinted with permission)

Additional Reading: Section 5

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- Rubin S.M. & S.C. Fish. 1994. Biodiversity Prospecting: Using Innovative Contractual Provisions to Foster Ethnobotanical Knowledge, Technology and Conservation. *Colo. J. Int'l Env'tl. L. & Pol'y* 5:23-58.
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- The Manila Declaration Concerning the Ethical Utilization of Asian Biological Resources. 1992. Resolutions ratified by the Seventh Asian Symposium on Medicinal Plants, Spices and Other Natural Products (ASOMPS VII), Manila, Philippines, February 2-7. *Flora Malesiana Bulletin* 11(1):30-32.

AN OVERVIEW OF THE WORLD MARKET FOR GENETIC RESOURCES IN THE ETHICAL PHARMACEUTICALS INDUSTRY:

MARKETING VALUE-ADDED NATURAL PRODUCTS IN A COMPETITIVE WORLD

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Part 1. Definitions:

Genetic resources or natural products = organisms which yield the genes and chemicals found in nature.

Biodiversity prospecting, natural products research, or "bioprospecting" = the process of developing genetic resources into marketable goods, usually associated with chemical or biochemical properties of genetic resources.

Equitable bioprospecting = bioprospecting in developing countries which links the process of pharmaceutical research and development to conservation and community development.

Part 2. Why equitable bioprospecting?

The combined market worldwide for pharmaceuticals, agrochemicals and seeds is over \$250 billion annually and genetic resources provide the starting material for a significant portion of this market^{1,2}. Pharmaceuticals comprise the largest share of this, at approximately \$160-170 billion annually, and it is estimated that some 40% of prescription drugs are derived from natural sources^{3,4}.

This shopping list of genetic resources yielding pharmacologically-interesting compounds includes microbes such as fungi and bacteria, plants, insects, and marine organisms. Besides investigating small molecules under 1000 molecular weight, several biotechnology companies are also actively studying complex proteins such as enzymes for commercially valuable properties. The isolation of enzymes from "extremophiles", microbes adapted to living in harsh environments such as hot springs and salt ponds,

is of particular interest to biotechnology companies seeking to market new research tools.

Bioprospecting research typically requires chemical or biochemical extracts of genetic resources. The amount of extract required for natural products screening is minimal, not more than 100 to 200 milligrams of dried chemical extract is needed to perform exhaustive screening for pharmacologically-active small molecules. For extracts derived from plants, this corresponds to harvesting approximately 500 to 1000 grams of dried plant material. Such small amounts of chemical extract can contain hundreds or thousands of complex organic molecules each.

Put another way, bioprospecting requires not so much the actual physical sample as the **information** contained within it, in this case information in the form of chemical structures. Therefore, because bioprospecting, at least the initial stages of research and development, requires only small amounts of material yielding useful information on chemical structures, it is in theory well-suited for the sustainable use of natural resources.

Part 3. The process of pharmaceutical research and development.

Pharmaceutical research and development is a costly and time-consuming process, requiring an investment of some 10-15 years and \$200-300 million per successfully-marketed new drug⁵. Most of this financial risk is incurred in the *later* stages of research and development, making pharmaceutical research and development an expensive and risky lottery.

The process of pharmaceutical research and development can be conveniently divided into a series of value-adding steps, shown in diagram 1, and briefly summarized below:

1. Inventory and extraction. Natural products screening begins with a biological inventory. For botanicals, typically several kilograms of wet material are collected and dried, to yield several hundred grams of dried plant matter. Marine samples are collected and frozen immediately. Microbes such as fungi and bacteria are cultured from soil or other organic or biological sources and grown in large fermentation cultures. Insects are collected to at least one hundred grams dry weight.

Natural products samples are extracted with organic solvents, sometimes with solvents of differing polarity, and dried. Botanical samples are sometimes treated to remove tannins to reduce the concentration of interfering cytotoxic compounds.

2. High-throughput screening (HTS). Natural products extracts are tested for the presence of pharmacologically-interesting compounds by screening with

biological assays. Bioassays are usually designed to test the response of a single protein or cell type (for example, cancer cells) to the extract. Proteins are chosen based on their role in causing a particular disease, and are isolated through state-of-the-art biotechnology methods. Bioassays designed with individual molecular targets such as proteins are sometimes called "mechanism-based" screens, because a positive result implies that a particular chemical in the natural products extract is interacting with the target protein of the bioassay and hence the molecular mechanism of action is known beforehand. Gaining the means to test natural product samples through molecular or cellular screening adds significant value to the samples.

In technology-intensive screening, all bioassays are automated through robotics systems costing millions of dollars. Fully automated bioassays are capable of screening a thousand samples overnight, hence the term "high-throughput screening" or HTS. Biotechnology or pharmaceutical companies invest significant resources in designing their own proprietary screens. Designing a good screen is the key to success in natural products research, since screens must lead to the identification of unique and pharmacologically-interesting molecules--with novel mechanisms of action--before companies will invest in further research and development.

Not all screens are proprietary, nor are they all high-throughput. Some screens can be adapted for use in developing-country laboratories, particularly those which utilize simpler bacterial or yeast-based biological assays.

3. Lead compound identification and optimization. The purpose of natural products screening is to identify unique and pharmacologically-interesting compounds known as leads. Leads are like molecular clues--they are the building blocks from which new and commercially-valuable drugs can be designed. It is rare that commercial drugs are isolated in final form directly from natural sources. One example of this is taxol, an anticancer drug originally isolated (in the form which has been approved for market) in the United States from the bark and needles of the Pacific yew tree, *Taxus brevifolia*⁶.

More often, naturally-derived lead compounds provide the starting point for the design of more effective synthetic compounds. For example, topotecan⁷, another anticancer drug showing great promise in human clinical trials, is a synthetic compound based on camptothecin⁸, a natural product isolated from a Chinese tree, *Camptotheca acuminata*.

Lead compounds are isolated by organic chemists from natural products extracts, which may contain hundreds of organic chemicals, through a process known as "bioassay-guided fractionation". The original bioassay which indicated the presence of pharmacologically-interesting molecules is used to

test increasingly-refined fractions of the original extract to confirm the presence of the active molecules. Eventually the molecules are purified to homogeneity, and their chemical structure is determined with the help of a complex and extremely expensive machine (cost is approximately \$500,000) known as a two-dimensional nuclear magnetic resonance imager (2-d nmr).

Purified molecules with unique structures or with interesting mechanisms of activity are designated as lead compounds, and are retested with a confirming bioassay. Those leads which are still active may be "optimized" or chemically modified to increase their therapeutic index. Therapeutic index is defined as the ratio of the concentration of compound which is toxic to the patient versus the concentration which effects a cure. Biotechnology and pharmaceutical companies are most interested in lead compounds with a therapeutic index in excess of one thousand, i.e. the curative dose is one thousand times less than the toxic dose.

4. Animal or "preclinical" testing. In order to help determine therapeutic index, animals are used to test the effects of the lead compounds on living systems. Animals are used to determine the toxicity of the compound, and where animal models of a human disease are available, animals are also used to test the efficacy of the compound. Animals are also used to determine the "pharmacokinetics" of the compound, or how it is metabolized within the body after administration.

5. Testing drug candidates in human clinical trials. Lead compounds or optimized compounds derived from natural products leads, which yield good preclinical data and have an acceptable therapeutic index, are candidates for human testing. Drug candidates are patented by the biotechnology or pharmaceutical company and, in the United States, are presented to the U.S. Food and Drug Administration (FDA) for permission to begin human testing. Companies must file an Investigational New Drug (IND) application with the FDA to obtain this permission. Human testing is extremely costly and time-consuming in the United States, although the FDA will likely be pressured by the U.S. Congress to shorten this process in years to come.

Companies whose drug candidates still show efficacy and good therapeutic index in human clinical trials petition the FDA with a New Drug Application (NDA) for final approval to market the new drug.

Part 4. The economics of pharmaceutical research and development.

The conventional wisdom on the economics of pharmaceutical research is that for every 10,000 samples which are screened, approximately 10 will yield interesting lead compounds⁹. Of these 10 leads, perhaps one may show sufficient promise in animal testing to be approved for human clinical trials

as a new drug candidate. Only about 10% of these drug candidates are actually approved by the FDA for sale in the United States. See diagram 2.

This means that drug firms must screen some 50-100,000 different samples in order to find one profitable drug! This extremely low rate of return on random screening of biological samples explains the emphasis placed on high-throughput screening. The more samples which a company can run through its screens, the greater its chances of reaching a profitable endpoint. Pharmaceutical companies are always seeking ways to lower this high level of risk involved in finding lead compounds or new drug candidates--perhaps creating significant opportunities for developing countries willing to invest in bioprospecting programs.

One way in which the pharmaceutical industry lowers the risk of screening is to work closely with small biotechnology firms. In the United States alone there are over 1000 biotechnology "start-up companies", small companies founded with some capital and a few good ideas for doing pharmaceutical research and development. Essentially, it is the function of the biotechnology industry to provide material for pharmaceutical development, in the form of extracts, lead compounds or new drug candidates, to the pharmaceutical industry. In some cases biotechnology companies provide services too, such as high-throughput screening or animal testing. This is depicted in diagram 2.

Performing human clinical trials is beyond the means of most biotechnology companies. It is the large multinational pharmaceutical companies, of which there are only a few dozen worldwide, which have the resources to engage in long-term human trials of new drug candidates. Supporting biotechnology companies engaged in pharmaceutical screening lowers the risk and augments the intellectual capacity of pharmaceutical firms, supplying far more lead compounds than the firm's own in-house screening group could accomplish on its own. In some cases, pharmaceutical firms are willing to invest in biotechnology companies with the understanding that the investor will get the right of first refusal to any interesting value-added products generated by the biotechnology company.

The increasing economic potential of value-added natural products research is depicted in diagram 2. Inventoried natural products extracts represent the lowest end of the value-added chain. Typically, extracts will trade for tens to hundreds of dollars. Screening extracts with the right biological assays can increase the value of extracts testing positive by two-fold or more. Choice of bioassay is extremely important here--it is strongly recommended that developing-country scientists wishing to seek out a business relationship with a biotechnology or pharmaceutical company consult closely with the potential business partner before adopting any screening technology. Isolating interesting lead compounds from extracts

testing positive on bioassays can increase the value by ten-fold or more.

Lead compounds which have interesting structures and novel modes of action (this is often evaluated by the original choice of biological assay) and which have been evaluated in preclinical animal trials and show good pharmacokinetics and therapeutic index can trade for tens of thousands of dollars each. At this point, lead compounds or new drug candidates may be patentable, and many firms will prefer to patent promising candidates and then attempt to license patented compounds to pharmaceutical companies for further research and development.

Because the investment in new pharmaceutical drugs is so high--\$200-300 million and 10-15 years per successfully-marketed new drug--biotechnology and pharmaceutical companies are only willing to invest in research and development in therapeutic areas where the market potential is very high. Pharmaceutical companies are reluctant to do research on diseases with a potential to earn less than \$100 million a year in drug sales. Rarely, drugs will earn up to \$1 billion a year. This explains in large part why most new drugs are targeted against diseases such as cancer, heart disease and stress-related conditions common among the populations of Northern industrialized countries. The economic market for tropical infectious diseases is insufficient to attract much Northern capital, a sad state of affairs but one which equitable bioprospecting may one day ameliorate. This possibility is discussed in part 5.

Compensation for value-added materials provided or value-adding services rendered by biotechnology companies for pharmaceuticals firms usually include a mix of up-front compensation and royalty rights. Up-front compensation will vary with the trade value of the biological material as depicted in diagram 2. Royalty percentages increase as one ascends the value-added chain of research and development. Royalties for providing natural products extracts are quite low, normally 1-3%--although much closer to 1% usually! For a successfully-marketed drug earning between \$100 million and \$1 billion per year, this would correspond to royalty income of between \$1-3 million annually to a maximum of \$10-30 million. Royalties for providing lead compounds or new drug candidates can go as high as 10-15%. Ten percent royalties would correspond to an annual income of \$10 million to as high as \$100 million.

Relying on the possibility of royalties alone will rarely if ever produce income from bioprospecting. Because the likelihood of any one natural products sample yielding a new pharmaceutical drug is on the order of 1 in 100,000, all bioprospecting deals between biotechnology and pharmaceutical companies include significant up-front compensation to cover the costs of the research services plus a reasonable profit margin. No well-informed natural products research group would give away biological samples for free to a commercial research and development firm in exchange for the promise of

future royalties. In other words, biotechnology companies profit from the *process* of natural products research, not just from the *end-products* of this research.

Part 5. Strategies for marketing value-added natural products in a competitive world.

It is the purpose of this section to argue that biodiversity-rich developing countries have the opportunity to engage in value-added natural products research just as biotechnology companies of Northern industrialized countries do today. There is an enormous need for new sources of "molecular diversity" used as the starting material for pharmaceutical research and development by the biotechnology and pharmaceutical industries. For example, one biotechnology company known as Oncogene Sciences, Inc. has set a goal of building the technological capacity to screen some *one million* samples per year. Firms such as this which utilize bioprospecting, among other methods, to stock their library of molecular diversity will be unable to attain their goal without new and affordable sources of natural products.

The pharmaceutical natural products market is highly competitive. Natural products brokers already exist, as do compound "libraries" available for lease. Botanical gardens sometimes play the role of collector for drug firms, winning contracts worth hundreds of thousands or millions of dollars to supply extracts for screening. Additionally, there is currently steep competition with natural products from other sources of molecular diversity, including such synthetic sources as "medicinal chemistry libraries" (pure synthetic compounds with interesting chemical structures) and, especially, "combinatorial chemistry libraries". Combinatorials are mixtures of synthetic polymers prepared in a manner which incorporates random variations in structure leading to enormous variety in polymer sequence.

Combinatorials are often synthesized with convenient chemical properties which make purification and structural determination relatively cheap and simple--a significant advantage over natural products, which may require repeated and costly rounds of purification followed by sometimes difficult structural determinations. However, combinatorial libraries are limited by the ingenuity of the chemists who design them. Natural products, designed by Nature over the course of a billion years and uncountably many trials, suffer no such limitations. For example, there are an estimated 250,000 to 750,000 species of higher plants in the world. It has been estimated that no more than 5,000 have been *exhaustively* screened for pharmacological activity¹⁰. With an estimated 10 to 100 million total species on the planet Earth, over 50% of which are insects¹¹, it is likely that natural products will generate economic interest for years to come.

The key to generating interest in natural products among biotechnology, pharmaceutical and agrochemical firms is to market biological samples in a manner which lowers risk for the partner firm while still maintaining profitability for the supplier.

The following section outlines marketing strategies for developing-country organizations wishing to market natural products to the pharmaceutical, biotechnology and agrochemical industries. These strategies are based on the results of a market survey performed by the author in 1994 of some two dozen biotechnology and pharmaceutical firms in the United States and the United Kingdom. The strategies presented here presume a basic level of technical expertise in natural products research, and emphasize marketing natural products extracts as a way to get started in equitable bioprospecting. **However, it is essential that bioprospecting organizations seek to acquire the technology to ascend the value-added chain of research and development in order to maximize returns.**

It is impossible to estimate the size of the market for extracts of genetic resources, because companies do not publish their sample acquisition budgets. However, it is likely that the total market for extracts for screening purposes is less than \$100 million, perhaps no more than a few tens of millions of dollars. Therefore, it is preferable to trade genetic resources not only for monetary compensation but for technology as well, even if this means giving up some short-term monetary gains, in order to add value to samples. In so doing, nations will move beyond the role of raw materials suppliers to become marketers of value-added lead compounds, drug candidates, or even safe and effective pharmaceuticals based on natural products.

Some strategies for marketing genetic resources:

a) Offer reliable natural products supply services. Offering reliability with a developing-country supplier in a world made uncertain by the impact of the Biodiversity Convention on access to genetic resources is to secure a comparative advantage in the bioprospecting marketplace. Reliability includes correct taxonomic identification of samples, good quality control over extracts including freshness and reproducibility, and a reliable or even guaranteed source of resupply for those samples of continuing interest to partner firms. Reliability also takes the form of working with the full support of government, adhering to national and local regulations on access to resources. When community land is involved, reliability also includes ensuring that issues like obtaining prior informed consent and ensuring equity in resource development are dealt with up-front in a transparent manner.

b) Add value to natural products extracts wherever possible. When working with plant extracts, offer a service to remove tannins from the extracts for an

additional fee¹². Offer to supply for a fee ultraviolet absorption spectra, which are molecular fingerprints useful in estimating the chemical content of the extracts. Charge for extracts according to the inventory and extraction services offered, e.g. charging more for fresher samples or extracts prepared with more complex protocols involving combinations of organic solvents. Offer extracts which are prepared in a manner which is automation-friendly. For example, all laboratory robots are compatible with "96-well microtiter plates" designed to hold 96 separate samples at a time. Aliquotting samples into 96-well plates saves time for commercial researchers, who need only thaw the samples and place the pre-loaded plates on their machines to begin a series of biological assays.

Besides offering whole extracts, consider offering purified compounds or even partially-purified classes of compounds, e.g. offering samples as "sterol fractions" or "alkaloid fractions" etc., charging more for purified or partially purified samples than for whole extracts. Offer to screen samples with simple bioassays which are accepted by partner firms as a valid means to add value to samples (check with the firm first!). For example, antimicrobial assays run with bacterial or fungal cultures, or, better still, molecular target-based screens utilizing individual protein targets cloned into bacteria, yeast or insect host cells. Although inserting target protein genes into foreign cells through biotechnology manipulations is a relatively complex process, actually using screening systems based on growing bacteria, yeast or insect cells is relatively cheap and "user-friendly." Acquiring these screening systems may be possible by trading for them in exchange for access to genetic resources.

c) Get involved in marketing microbial extracts. Microbial diversity is enormous¹³, and the market for microbial fermentation products is larger than that for plant extracts. Soil samples are a favored source of microbes, including bacterial and fungi. Fermentation technology is often proprietary however, and gaining this technology will most likely entail working closely with a single screening company willing to invest in a microbial isolation facility in the source country. Do not underestimate the value of 'charismatic microflora' as a source of immediate income for other bioprospecting activities.

d) Explore the possibility of marketing ethnobotanical data with genetic resources. Although there is not a large market for screening medicinal plants known from traditional knowledge of herbal medicine, there is a growing body of data which shows that screening herbal remedies increases the success rate in finding interesting lead compounds. It may be possible to offer genetic resources with data on traditional uses for a premium price. However, be certain to obtain prior informed consent from any traditional community from which one is seeking ethnobotanical data.

e) Develop a reputation over time as a reliable business partner, and

bioprospecting firms will seek you out as a new supplier.

Some pointers for designing equitable bioprospecting contracts:

f) Trade genetic resource samples intelligently. Biological inventories are in progress around the world, funded by the Global Environment Facility, the U.S. National Science Foundation, and other scientific and development assistance agencies. Although most inventories are conducted for the purpose of basic taxonomic research, these inventories could be modified to collect larger quantities of material for bioprospecting.

Avoid selling extracts or otherwise giving up ownership rights. Lease extracts for a fixed period of time. Extracts which have been screened once can be remarketed to other companies, generating additional income with no additional investment in the samples. For this reason, it is important to collect sufficient material when inventorying for bioprospecting to allow repeated leasing of extracts. Protect the security of samples by sending coded extracts, to avoid tempting partner firms to seek third parties for sample resupply. Send the minimum extract required for high-throughput screening and bioassay-guided fractionation. Typically, firms will insist on receiving hundreds of milligrams of dried extract per sample. However, a single bioassay will usually require no more than several tens of micrograms.

g) Use equitable bioprospecting as a mechanism to further research on tropical disease. With some 600 million cases worldwide of tropical disease, it is an unfortunate reality that only 15% of the world market for prescription drugs is found in developing countries, primarily Asia and Latin America¹⁴. At the same time, the World Health Organization estimates that the proportion of the world's population that uses traditional medicine is 80%¹⁵. Trading genetic resources for access to bioassays useful for tropical disease research is one way to increase the number of lead compounds active against these diseases. These bioassays could be used to identify and develop new prescription pharmaceuticals.

Because most prescription pharmaceuticals are too expensive for the majority of developing-country populations, another intriguing use for these bioassays is as a tool to validate traditional medicinal uses of plant extracts. Combining this scientifically-controlled validation with animal toxicity data would allow calculation of therapeutic indices for traditional medicines. In this manner, developing-country scientists would be able to produce low-cost "phytomedicines" readily accessible by developing-country populations.

DIAGRAM 1

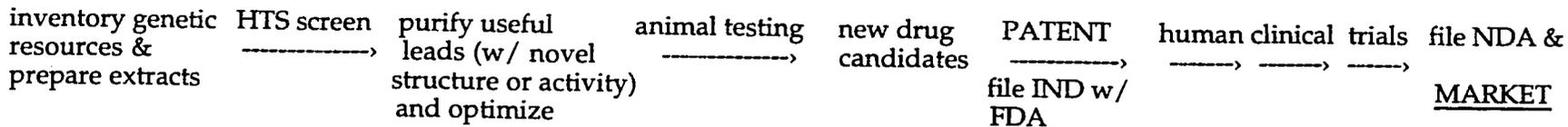
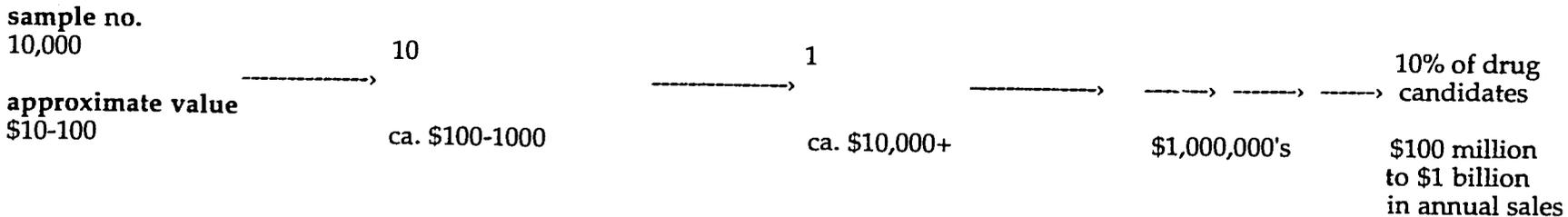


DIAGRAM 2



[----->BIOTECHNOLOGY & PHARMACEUTICAL FIRMS ----->] [----->PHARMACEUTICAL FIRMS ----->]

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FINDING THE LINK BETWEEN CONSERVATION AND DEVELOPMENT



BIORESOURCES DEVELOPMENT AND CONSERVATION PROGRAMME
PROGRAMME DE DEVELOPPEMENT ET PRESERVATION DES RESSOURCES BIOLOGIQUES

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BDCP - Conservation and Sustainable Development - Stakeholders Approach

###

The Bioresources Development and Conservation Programme (BDCP) is a platform for collaborating group of natural products scientists, environmentalists and industrialists aimed at the development of conservation programmes which link the developmental needs of people living in tropical countries with the protection of the environment. BDCP is a non-governmental and not-for-profit international organization.

THE BDCP MISSION

###

To encourage the appreciation of tropical forests as biological resources which could be used as instruments of sustainable development.

To link the well-being of tropical forests with the health of human inhabitants by providing affordable health care for people living in tropical countries through the development of plant based medicines for the treatment of tropical diseases.

To assist indigenous communities, private institutions and individuals in tropical countries to enter into biodiversity prospecting business (local, national, and international) that guarantees them good returns for their labour while at the same time protecting forest resources.

To seek international support for critically under-funded community based biodiversity conservation projects.

To develop forestry management programmes based on respect for indigenous or traditional ecological knowledge (TEK).

To establish partnership arrangements with Northern based institutions and agencies in which indigenous communities are recognized as the primary stakeholder and that human needs should be the paramount consideration in any conservation and development projects.

To develop the technical capacity and the scientific capability in tropical countries that will enable them to study their own environmental problems and to participate in the development of their biological resources.

To study the factors that influence conservation of biological diversity of tropical forests and to encourage exchange of ideas, data and experience among experts working on the subject.

ORIGIN

###

BDCP was established in 1991 by a resolution at the inaugural meeting of the Steering Committee at the University of Nigeria, Nsukka. The international Programme was, however, formally established during the Earth Conference in Rio (UNCED) at an African forum on Biodiversity Conservation as a network of scientists, industrialists, and policy experts who are interested in the issue of providing a link between conservation of tropical forests and economic development. Membership of BDCP and participation in the projects sponsored by the organization are open to institutions, companies and individuals interested in development and conservation biological resources in the tropics - with special reference to Africa.

To the founders of BDCP, most of the environmental problems in Africa are traceable to the dynamics of the tropical ecology, the increased demand for agricultural products as food for an ever increasing population, and the pressure on poor communities to provide cheap industrial feed-stock for developed nations at prices determined by so-called "market forces". In attempts apparently aimed at improving agricultural production in Africa, several well meaning organizations have compounded the situation by importing inappropriate models of agriculture used in ecologically different areas of the world into Africa. The result of these experiments has been an unmitigated disaster of such magnitude that the human suffering caused by these experiments has no parallel in human history.

PROGRAMME AREAS

###

BDCP focuses its activities in tropical countries with special emphasis on the continent of Africa. The major activities center around the following themes:

- * Collection and collation of available information on the uses of African plants, with special reference to indigenous food crops, medicinal and aromatic plants, and industrial crops.
- * Monitoring of selected ecological sensitive zones for biodiversity loss.
- * Conservation of tropical African forests by encouraging basic research on various land use options and on the sustainable utilization of tropical forest plants.
- * Stimulation of public awareness and concern about the vanishing resource base of tropical agriculture, and to support the activities of public interest groups that are working on these issues and foster co-operation and communication between them.
- * Initiation and encouragement of efforts by local communities for the conservation of biodiversity as a feasible tool and exploitable resources for sustainable economic development.
- * Encouragement of the establishment of small-scale agro-industrial and marketing enterprises, and similar ventures which seek to empower the poor and the powerless to derive maximum benefits from their habitat.

THE APPROACH

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BDCP is essentially a cooperative of independent scientists, policy analysts, industrialists and institutions concerned with the deteriorating condition of life in the tropical parts of the world. It serves as a *catalyst* for projects selected for support by its Scientific and Technical Advisory Committee composed of internationally renowned scholars. BDCP exploits its independent and non-governmental status to bring innovative management and technical support to grass-root development projects. It will serve as an intermediary institution to forge a link between primary stakeholders in tropical countries and often inaccessible developmental institutions. Capacity building and self reliance are the underlying tenets in all BDCP projects. The Programme is managed by the Executive Committee and the projects are implemented through National Programme Management Boards of experts drawn from various disciplines.

ACTIVITIES

###

In order to realize its goals, some pilot projects have been initiated and several others are being formulated with scientists from Africa and non-Africans interested in the continent.

1. Information Management

An off-line data base has been established to record information on the economic botany of African plants, including their botanical identification, medicinal uses, local names, chemical constituents, potential industrial application and reported pharmacological activities and toxicity profile. Our list presently has 1024 entries of major medicinal and aromatic plants used in the entire continent. A major inventory is scheduled to begin in Cameroon and Nigeria in 1994 which will provide information on economically useful species and data on forest dynamics of the area.

Collaborating centers have been initiated in various regions of the continent in order to generate a comprehensive inventory of available biological resources.

2. Social Forestry Projects

Rural communities have been assisted in cultivating selected tree crops for food, fuel-wood, and as barriers in farms to check erosion. A trial deep forest farm has been completed in the Akwanga District of the Cross River State of Nigeria to experiment on the cultivation of *Physostigma venenosum*, a highly prized medicinal plant, as an alternative use of the habitat.

Similar farms are proposed for selected plants found useful as possible raw materials for industrial production. The difference between these farms and conventional agricultural farms is that the cultivation is within the forest system, with minimal disturbance of the natural ecosystem. A fundamental requirement for this type of farm is that there should be minimal land clearing and no deforestation of any kind in the farm site.

3. Biodiversity Monitoring

BDCP is collaborating with various national and international agencies in West and Central Africa in conducting an inventory of flora and fauna in the forest of that region. Small plots are subjected to detailed study and monitored at specified intervals. The project will provide basic data which will help in the development of better forest management strategies. The Programme also plans to assist communities in the establishment of parks, nature reserves, and biological gardens in locations close to protected areas to serve as buffer zones and extractive reserves.

4. Development of Private Sector Initiated Enterprises Based on Sustainable and Profitable Utilization of Bioresources

A major aspect of this Programme is KIBORD (Kates Institute of Bio-organic Research and Development) project. KIBORD is a private sector initiative, which in collaboration with the biological sciences, pharmacy and chemical engineering Departments of Nigerian universities is investigating tropical African plants as possible raw-materials for the cosmetics, pharmaceutical and food-flavor industries. The KIBORD project focuses on the South-Eastern rain forest region of Nigeria, in the Cross-River/Niger/Imo river basin. The area is ecologically sensitive and represents the western boundary of a contiguous rain forest range that stretches up to central Africa, including the rain forests of Cameroon, Gabon, Equatorial Guinea, and Congo. Through KIBORD several small scale biodiversity projects have been established by communities and "thrift societies" in the region.

5. International Congress on the Industrial Utilization of Tropical Plants and Conservation of Biodiversity

One of the main projects executed by BDCP in 1993 is the hosting of an international congress on the Industrial Utilization of Tropical Plants and Conservation of Biodiversity at Enugu, Nigeria on February 14-19, 1993. The congress which was co-sponsored by the *Rainforest Alliance*, New York had as its sub-title "Finding the Link between Conservation and Development". The main theme of the Congress was the development of a holistic approach in which human needs and habitat conservation can both be accommodated. The subject was explored through plenary sessions and panel discussions on the following themes:

- * Utilization of Tropical Medicinal and Aromatic Plants
- * Sustainable Exploitation of Industrial Tropical Crops
- * Extractive Reserves and Biodiversity
- * Agroforestry Strategies
- * Intellectual Property Laws, Genetic Resources, and the Rights of Indigenous People.

The congress was very successful and attracted participants from many countries, and covering diverse disciplines such as Forestry Management, Pharmacognosy, economics, anthropology, botany law, medicine, ethnobotany, ecology, zoology, geography, etc. A book of proceedings is being edited. The Second Congress has been scheduled for September 1995.

6. Development of New Antiparasitic Agents Based on Plant from Africa

BDCP is collaborating with laboratories in the U.S.A and Europe in the investigation of novel plant derived compounds and extracts for the treatment of three of the most prevalent and drug-resistant tropical protozoan diseases --- malaria, leishmaniasis and trypanosomiasis. Although these diseases affect millions of people throughout the tropics, pharmaceutical companies in industrialized countries have shown little interest in developing antiparasitic medications because the greatest demand for such drugs are from people in countries that can least afford the high prices that new drugs demand. BDCP scientists are currently collaborating with U.S. scientists in the development of six potential broad-spectrum antiprotozoal agents already identified through its screening projects. Part of BDCP plan is to develop plant extraction technology in the two source countries so that two of the plant extracts could be formulated as low-cost *phytomedicines* which will be made available to local populations at affordable prices.

7. Ethnobiology and Field Taxonomy Training Course

The first ethnobiology and field taxonomy course was conducted at Nsukka, Nigeria in November, 1994 to train field taxonomist and ethnobiologist for our major project on ethnobotanical inventory and economic value assessment of plants in the eastern states of Nigeria.

There were 18 participants in the course, drawn from ten states in our target area of Nigeria, the Federal Environmental Protection Agency, and Natural Resources Conservation Council. The courses were taught by 26 lecturers, including 5 core staff and 21 guest lecturers. The participants also benefitted from guest seminars given by three visiting scientists from U.S.A. The program was highly successful and we hope to publish the training manual during the next few months so that it could be used for future sessions and as a guide to others interested in conducting similar courses in Africa.

8. Institutional Capacity Building

BDCP is assisting the Phytotherapy Research Laboratory at the University of Nigeria in the procurement of basic equipment and reagents for its work on African medicinal plants. The Programme also assisted the Cross River State University Uyo to establish a medicinal plant garden to teaching undergraduates.

The Programme sponsored a participant at the First Biodiversity Monitoring Course organized by the Smithsonian Institution in 1993.

RESOURCES

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The Bioresources Development and Conservation Programme relies entirely on grants and specific project funding for its activities. Although BDCP was conceptualized as a "not for profit", non-governmental institution, the program is designed to generate its funds independent of governments' direct assistance. It is envisaged that eventually most of its activities will be financed from royalties and trust funds.

Current administrative costs are covered mainly from contributions from Nigerian based Biotech Development Agency (BDA) and KIBORD.

The Programme received assistance from the following organizations for the 1993 International Congress on Industrial Utilization of Tropical Plants and Conservation of Biodiversity: Biodiversity Support Program (c/o WWF, Washington D.C., U.S.A), Bristol-Myers Squibb Pharmaceutical Research Institute, Indena, Inverni della Beffa Milan (Italy), Monsanto Company, St Louis, Mo (U.S.A.), National Institute of Pharmaceutical Research and Development, Abuja (Nigeria), One World Now, Plantation Botanicals, Inc., Shaman Pharmaceuticals, Inc., Starks Associates, Inc., and Sterling Products (Nig.) Plc.

BDCP in collaboration with Walter Reed Army Institute of Research, Washington, D.C., the Smithsonian Tropical Research Institute, the University of Yaounde (Cameroon) and the University of Nigeria, Nsukka (Nigeria) is one of the recipients of a grant under the International Cooperative Biodiversity Group (ICBG). The ICBG funded jointly through an interagency agreement between the U.S. National Science Foundation, the Agency for International Development and the U.S. National Cancer Institute is administered by the Fogarty International Center at the National Institutes of Health.

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Policy for the acquisition of natural product source samples

Glaxo Research and Development (GRD) is aware of, and sensitive to, issues relating to biodiversity and conservation. In particular, GRD recognises the importance of matters considered by the International Biodiversity Convention at the United Nations Conference on Environment and Development in Rio in 1992. GRD understands the impact that unauthorised and/or unrestrained removal of natural materials from their indigenous habitats can have on the environment and economy of a country.

GRD recognises that various natural materials, such as plants, microorganisms, algae and marine invertebrates, are a valuable source of novel biologically-active molecules that may serve as templates from which new therapeutic drugs can be derived. GRD works with small quantities of natural materials to discover bio-active principles that, in turn, allow lead compounds to be identified. In the vast majority of cases, further supplies of such lead compounds and derivatives are synthesised by Glaxo's own medicinal chemists.

In seeking access to natural materials, GRD's policy is to collaborate with organisations that possess the expertise and the authority to obtain such materials from whatever source. Agreements will be concluded with prospective sample suppliers only when they can provide documentary evidence that they have permission from appropriate government authorities to collect such samples.

Samples of plants and other organisms must be classified taxonomically and their supply must be reproducible and sustainable. GRD will neither seek, nor knowingly support, the collection of endangered species.

In collaborating with *bona fide* suppliers, GRD's practice is to reimburse them for the costs incurred in collecting natural product source samples and to reward their expertise (e.g. taxonomic classification). All costs of freight of natural materials are borne by GRD.

GRD's Material Transfer Agreements may make reference to intermediate forms of compensation, and may involve a financial benefit payable to the supplier in the event that GRD is able to develop a commercial product as a consequence of screening the natural products supplied. The magnitude of this payment will recognise the relative contribution of the discovery of the bio-active principle to the subsequent development of the commercial products. This does not normally entail a transfer or sharing of intellectual property rights by Glaxo. In addition we ask that a significant portion of this payment will be returned to the source country to support scientific training and education at the community level.

A distinction is drawn between supply of natural materials for drug discovery and the broader philanthropic support of efforts to conserve resources of which these materials are a part. GRD as a company with interests in basic research applications of natural materials, negotiates purchase terms on the basis described above for sample acquisition. Conservation support *per se* is a matter for consideration by the Appeals Committee of Glaxo Holdings p.l.c.

Amended 6th January 1994



Catharanthus roseus, the source of two important anti-cancer medicines

SECTION 6

LEGAL TOOLS FOR BIOPROSPECTING AGREEMENT

SECTION 6: LEGAL TOOLS FOR DESIGNING BIOPROSPECTING AGREEMENTS

Introduction:

This section explores the use of contracts as tools for designing equitable bioprospecting collaborations. Developing a truly equitable bioprospecting collaboration requires familiarity with contract law and with the concepts of tangible and intellectual property. The first two papers presented here explore these concepts and introduce a special type of contract called a Material Transfer Agreements. Material Transfer agreements are contracts that can define rights to biological samples, including genetic resources used in bioprospecting. Material Transfer Agreements are useful because they can be written in form-letter format. These "pro form" contracts can then be adapted to a wide range of uses with little modification.

The paper presented by Marianne Guérin-McManus, a "typical" bioprospecting contract is analyzed clause by clause. The contract discussed here is more comprehensive than most Material Transfer agreements, and it is noteworthy because it addresses issues raised when working with indigenous people and their traditional knowledge. This document is followed by the Summary of Terms of the original agreement between INBio and Merck & Company Inc., signed in 1991. Lastly, an example of a bioprospecting contract prepared by INBio for use with a non-commercial research organization (representing for example academic scientists) is presented. This contract is fully "redacted", meaning all of the specific numbers, such as royalty rates and exclusivity periods, have been removed.

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Rights Agreement (redacted version)

Additional Reading: Section 6

Downes, D. *et al.* 1993. Biodiversity Prospecting Contract. *In Reid, et al (eds.), op cit.*
Laird, S.A. 1993. Contracts for Biodiversity Prospecting. *In Reid, W., et al (eds.).*
Biodiversity Prospecting: Using Genetic Resources for Sustainable Development.
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Biological Materials Transfer Agreements

“Neither a borrower, nor a lender be; For loan oft loses both itself and friend,
And borrowing dulls the edge of husbandry.”⁵

Michael A. Gollin

Researchers routinely lend samples of organisms, tissues, seeds, cells, extracts, and other biological materials without payment changing hands. While there is little doubt that this informal practice of “professional courtesy” has accelerated the pace of scientific discovery, recent cases point out that the transfer of biological materials is becoming an increasing source of litigation. In the past ten years, drug-development companies and research institutions alike have been forced to divert considerable resources to litigation because there was no adequate written transfer agreement. To help prevent this possibility in your organization, it is important that everyone involved understand the legal implications of transferring biological materials.

A Costly Operation

A recent case involving the transfer of human tissue at the University of California at Los Angeles (UCLA) caught both the university and experienced drug-development companies off guard. A UCLA physician attempted to save a leukemia patient’s life by surgically removing the patient’s spleen. The operation was a success. But, instead of disposing of the spleen—as is the normal procedure—the physician moved the tissue to a lab, and subsequently developed and patented a T-lymphocyte cell line from it. Through UCLA, both Sandoz (East Hanover, NJ) and Genetics Institute (Cambridge, MA) took licenses for the invention.

Then, a summons arrived. The patient, whose spleen had been removed, sued the physician, UCLA, and the licensees for damages. The suit claimed that the defendants broke the law—the patient had never agreed to allow his spleen to be used for research. It went on to claim that any financial gain resulting from his spleen belonged to the patient. Did he have a case?

The California Supreme Court thought so: While it stopped short of allowing the patient’s claim that the defendants stole the spleen for profit, it did allow claims of breach of fiduciary duty and lack of informed consent. As a result, the defendants found it prudent to settle with the patient for an undisclosed sum.¹

Intellectual v. Tangible

What was wrong with using biological materials that would have been otherwise destroyed to develop a patentable invention? The first step to understand-

ing this case—and the legal implications of borrowing biological materials in general—is to recognize that the law distinguishes between two types of property rights.

The law views “tangible” property as material that is physically transferred from one researcher to another. The organisms, tissues, cells, seeds, and extracts that are collectively known as biological materials make up this type of property. This tangible property is distinct from the “intangible” or “intellectual” property that results from inventions based on these biological materials. In fact, the patents, trademarks, and copyright privileges associated with these inventions may be owned, transferred, and litigated separately from tangible property.

In the UCLA case, the patient claimed that there was no agreement to transfer possession of his tangible property—namely, his spleen. The patient claimed that because the law views the unauthorized use of tangible property as theft, he had a right to regain his property and any profits derived from its misappropriation. The intellectual property of the defendants never entered into this case.

It is interesting to note that the court was reluctant to recognize the patient’s spleen as personal property primarily because it was human tissue. Ever since the Thirteenth Amendment abolished slavery in the U.S., the assertion of property rights in the human body has been frowned upon. In contrast, with nonhuman material, a strong case could be made that its unauthorized use is theft.²

The Agreement’s Power

A biological materials transfer agreement is a powerful legal instrument for intellectual property as well. It has the advantage of binding the parties involved and their successors to an agreement continuously—before a patent issues, after it expires, and even if a patent never issues.

Most often it is the lack of this type of agreement that results in litigation. For example, in another recent case, a pet shelter operator “diagnosed” some of her cats as having an AIDS-like disease. She

The organisms, tissues, cells, seeds, and extracts that are collectively known as biological materials are considered “tangible” property under the law.

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It makes sense to reach at least a basic agreement before sending samples to another researcher—especially if the research has any commercial potential.

brought the cats to a virologist for analysis, telling him her tentative diagnosis. The virologist subsequently isolated a virus he called "feline immunodeficiency virus" (FIV) from the cat's blood and then proceeded to patent the virus, a diagnostic test for FIV, and an FIV vaccine. The shelter owner responded to these developments by suing to be declared a coinventor on the patents.

This costly intellectual property case could have been avoided altogether if the shelter owner and the virologist had entered into a transfer agreement from the outset that clearly defined the rights of each party. In this instance the court found that the shelter owner was not an inventor and had no rights under the patent.³

When even a simple transfer agreement is in place, it can provide important legal rights. For example, in the famous dispute between the Institut Pasteur (Paris, France) and the National Institutes of Health (NIH, Bethesda, MD), an Institut Pasteur researcher sent the NIH an HIV virus sample for testing. Attached to the sample was a form stating that the sample would not be used industrially or disseminated without prior written consent. An NIH researcher signed the form when the sample arrived. Later, the Institut Pasteur alleged that the sample was used in developing the HIV blood test and sought a share of royalties from the NIH.⁴ The case was settled when the NIH agreed to share the multi-million dollar royalties with the Institut Pasteur. The note that was attached to the sample was seen as an important factor in bringing about this settlement.

Writing the Agreement

As can be seen from these examples, without a solid agreement between a transferor and a transferee, certain statutory and implied obligations may or may not be imposed by a court. Therefore, it makes sense to reach at least a basic agreement before sending samples to another researcher—especially if the research has any commercial potential. Recording the terms of transfer in a written "biological materials transfer agreement" can preserve rights and avoid future disputes.

The transfer agreement does not need to be an overly complex document. But it is important that the key issues that might come up are addressed from the beginning. The first thing one wants to establish is what materials are being transferred. Care should be taken to avoid ambiguity in defining the materials and whether the agreement covers replicated or derived materials.

Next, the scope of the license needs to be defined. Typically, the transferor provides a nonexclusive, nontransferable, revocable license to the transferee. Usually the license states that the materials are for noncommercial research purposes only. The license may further specify who the authorized users are and the locations where the research will take place. The license's duration may be included, as well as a description of what is to happen to the materials at the agreement's termination. If the transferor feels confidentiality is important, the biological material and associated information may be subject to an obligation not to provide or disclose any information to third parties. Finally, to ensure that the terms of

the agreement are met, the transferor may insist on receiving a written report of the transferee's research results.

As further protection, the agreement can state that the transferee indemnifies the material supplier from liability that may result from the use of the material. It may be helpful to stipulate that the research will be conducted in compliance with applicable laws and regulations, such as NIH recombinant DNA guidelines on human testing. At the same time, the transferor may elect to disclaim any warranty about the nature of the material provided, or whether it infringes any intellectual property rights.

Consideration

In consideration for the transfer of the biological materials, the transferor has the right to receive compensation. This type of agreement is usually structured as a sale or a lease in which the recipient pays either a flat fee or a royalty for the material's use.

At present, most research-related transfers are made without payment. However transferors can look for other types of consideration besides cash. This can range from asking to be acknowledged in oral presentations, publications, and patents to reserving the right of first refusal for an exclusive license to any resulting patents. No matter how inconsequential these other forms of consideration may seem in the beginning, they should not be left to an informal understanding.

The agreement should also spell out the obligations each party must meet if a patentable invention results from the research. For example, who will prepare, prosecute, and maintain the patent? Also, any obligations to third parties should be revealed. For example, the National Cancer Institute (NCI, Bethesda, MD) distributes the natural products samples it has collected from sources around the world to researchers. The NCI's collection agreement with source countries states that if a commercial product is developed from the natural product, the researcher who develops it will use that country for the supply of further samples and pay the country royalties. Sample recipients are bound to these terms.

Conclusions

Biological researchers are accustomed to ignoring Polonius' famous advice.⁵ As the examples above have demonstrated, "borrowing" can do more than "dull the edge of husbandry"—it can get you in serious legal trouble. But a researcher need not go so far as to avoid being a borrower or lender altogether. Instead, drawing up a biological materials transfer agreement every time an important sample is transferred will prevent misunderstandings and help ensure that both parties get what they want—without loss of loan or friend.

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2. *Pioneer Hi-Bred Int'l. v. Holden Foundation Seeds, Inc.*, 31 U.S.P.Q. 2d 1385 (8th Cir. 1994).
3. *Brown v. University of California*, 31 U.S.P.Q. 2d 1463 (N.D. Cal. 1991).
4. These facts were held to state a claim for breach of contract against the United States' *Pasteur v. United States*, 814 F.2d 624 (Fed. Cir. 1987).
5. *Hamlet*, act I, scene III, line 75.

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Patenting Recipes From Nature's Kitchen

How can a naturally occurring chemical like taxol be patented?

MICHAEL A. GOLLIN

The "product of nature" doctrine is based on a 19th century view that human activity is fundamentally different from what occurs in nature.

Taxol, a natural product found in yew trees, has turned out to be one of the most promising cancer treatments to be discovered in decades. For biotechnologists, as well as natural-products researchers, a question often asked is, "How can a naturally occurring chemical like taxol be patentable?" It seems intuitively obvious that a product of nature should not be patentable. Common sense dictates that otherwise "inventors" would attempt to patent the air we breathe or the earth we walk on. As a rule of thumb, only the products of human innovation deserve intellectual-property protection.

Patent law suggests that this intuitive approach is correct if one is only trying to patent the bark of a yew tree. Under the U.S. Patent Law's section 101, yew bark would not ordinarily be considered a "manufacture" or "composition of matter" eligible for patent protection.¹ But if an inventor purifies or modifies a bioactive substance from the yew bark, then a new form that did not previously exist in nature has been created. Isn't this an example of human innovation that deserves patent protection?

Before you answer what seems to be a simple proposition, you must remember that inventors, patent practitioners, and the courts have grappled with the distinction between a product of nature and a human invention repeatedly over the past century. Even after all this time, drawing clear-cut distinctions remains difficult. However, some useful strategies have emerged for obtaining patent protection for natural-product based inventions. This article offers guidelines for inventors considering patenting these types of products.

The product of nature doctrine

The "product of nature" doctrine reflects the intuitive view described above. Simply put, it holds that the patent system should not allow inventors to appropriate recipes from nature's kitchen. Several older

rulings denied would-be inventors patents based on this reasoning. For example, in 1884 a patent for the artificial dye, alizarine, was rejected on the grounds that the same compound could be obtained from the root of the madder plant.² Later, a claim for using borax on the rind or skin of fresh citrus fruit to prevent decay was denied because the borax-treated fruit was essentially unchanged from the fresh fruit itself.³ In the 1948 *Funk Brothers* decision, a patent for a mixture of nitrogen-fixing *Rhizobium* bacteria was denied as a means to enhance the growth of legumes. The court reasoned that the bacteria species existed in nature, and therefore were, "free to all men and reserved exclusively to none."⁴

The "product of nature" doctrine is based on a 19th century view that human activity is fundamentally different from what occurs in nature. As René Dubos, a microbiologist and philosopher pointed out, this is a false dichotomy—we shape nature and it shapes us. Biotechnology challenges the 19th century view of patents because most biotech products use "natural" means to obtain innovative new products. As a result, intellectual property law has expanded to encompass these inventions. Fortunately, recent court decisions tend to focus on the more important and useful question of innovation—whether there is a novel and non-obvious invention, instead of whether the invention is somehow excessively "natural."

Although the "product of nature" doctrine has been roundly criticized, it remains the law and must be satisfied in order to obtain a patent. For example, in the landmark case of *Diamond v. Chakrabarty*, the Supreme Court approved a patent for a genetically modified bacteria. Two plasmids had been introduced into bacteria enabling them to consume oil—not their "natural" function. The court ruled here that the bacteria were a nonnaturally occurring "manufacture" rather than an unpatentable natural product.⁵

Questions you should ask

As is often the case in patent law, gaining patent protection for a natural-based product depends heavily on how the patent claim is drawn. It is often helpful for a biotech inventor to start the patenting process by

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asking a series of questions. Here are some of the questions every inventor should ask:

1. *Have I purified a compound from nature?*

Pure compounds do not exist without human intervention and therefore are usually allowable. Fishing out compounds from an organism's cellular soup, and concentrating them, requires human innovation. For example, purifying a prostaglandin is patentable.⁶ Typically, a purified compound's claim language will include phrases that state the compound is "99.49 percent pure," or "free from contaminants."

2. *Do I have an unpredictable use for a known natural component?*

Purification need not be the only criterion for making a claim. The previously known component of strawberries, 2-methyl 2-pentenoic acid, was patented as a strawberry flavor because it was not foreseeable that it was a significant flavor ingredient.⁷ Thus, unpredictable applications or uses of known natural products are patentable.

On the other hand, a component's purification may not be patentable if its use is considered obvious. For example, pesticidal preparations from ground cube roots—long-known in traditional agriculture to have a pesticidal effect—were not deemed patentable by one court.⁸

3. *Have I made an analog to the natural product?*

Where a natural product, like taxol, is already known, it may be possible to produce chemically modified homologs that have improved stability, activity, or other characteristics. If the result is not expected, or the method of preparing the homolog is not obvious, the compound may be patentable.

4. *Have I isolated a biologically pure culture or cell line?*

One should not jump to the conclusion that only purified compounds are patentable. A biologically pure culture can be patented. For example, purified *Streptomyces velloris*, used to produce the antibiotic lincomycin, was held patentable.⁹ Cell lines isolated from multicellular organisms can also be claimed: Hybridomas and genetically transfected host cell lines are examples.

5. *Have I "fingerprinted" something new or unexpected?*

When purification of a compound or culture is not possible, patentable claims can be drawn from the description of its "fingerprint." For example, instead of describing an isolated compound by its formal chemical name, functional terms may be used to describe the material: optical absorbance, immunological reactivity, enzyme sensitivity, or the process by which it is made (a "product-by-process" claim, see *Biol Technology* 11:475-476, April, 1993). This rule applies to naming an individual species or cell line as well.

6. *Have I made a new combination?*

Taking two known compounds and combining them may be patentable. But the inventor must be careful to prove that there was no suggestion in the prior art to combine them—and the combination must have unexpected properties.¹⁰ For example, curare is a poison used among South American Indians for hunting game. The tribal recipe combines *Strychnos guianensis* with admixtures. This formulation may

not be patentable because it was known historically. But variations on that recipe that produce medicinal uses might be patentable, as would combinations that allow new means to deliver the drug.

7. *Have I created a new method of preparation?*

Method claims can provide patent protection when composition of matter claims are unavailable. For example, in the alizarine dye case cited above, a claim to the process of preparing artificial alizarine would probably have been acceptable because a synthetic means to prepare the dye was not known.

8. *Have I created a new method of use for a known or even previously patented invention?* Where a compound is well known for one use, a new and nonobvious use for the compound will be patentable. For example, the use of taxol for something like treating arthritis would probably be patentable.

9. *Have I created a recombinant product that differs from a known naturally derived product?* The Federal Circuit ruled that a claim for "a human factor VIII: C preparation" purified from plasma was infringed by a recombinant factor VIII: C produced in a host cell.¹¹ Thus a recombinant gene product that has the same known structural and functional characteristics as a naturally derived one would not be considered a new invention. In these cases the inventor must opt for a process of use claim (see point 7, above) or a claim for the cell line (see point 4, above).

10. *Have I created a new plant or animal?*

As most readers know, utility patents may be obtained for new species of plants and animals as long as they satisfy the requirements of being "manufactured," novel, and nonobvious. In addition, plant patent protection is available for distinctive asexually reproduced species. Plant variety protection covers distinctive, uniform and stable sexually reproduced plants.

Conclusions

Intellectual property laws should assure that the fruits of human ingenuity are rewarded. This will add to the richness of our human environment—not detract from it. In fact, allowing these types of patents may do much to preserve what is "natural." It is now a matter of record that dozens of taxol-related patents have issued. Taxol analogs, methods of taxol synthesis, and assays for taxol bioactivity are all examples of how human ingenuity has improved upon the cancer-fighting recipes from nature's kitchen.

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2. *Cochrane v. Badische Anilin & Soda Fabrik*, 111 U.S. 293 (1884).
3. *American Fruit Growers, Inc. v. Brodley Co.*, 283 U.S. 1, 6 (1931).
4. *Funk Bros. Seed Co. v. Kale Inaugram Co.*, 333 U.S. 127 (1948).
5. 447 U.S. 103 (1980).
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7. *In re Kratz*, 592 F.2d 1169, 75, 201 U.S.P.Q. 71 (C.C.P.A. 1979).
8. *Dennis v. Pinner*, 106 F.2d 142 (7th Cir.), cert. denied, 308 U.S. 606 (1939).
9. *In re Bergy*, 596 F.2d 952, 201 U.S.P.Q. 352 (C.C.P.A. 1979).
10. *Amgen, Inc. v. U.S. Int'l Trade Commission*, 902 F.2d 1532, 14 U.S.P.Q.2d 1734 (Fed. Cir. 1990).
11. *Scrripps Clinic & Research Foundation v. Genentech, Inc.*, 927 F.2d 1565, 18 U.S.P.Q.2d 1001 (Fed. Cir. 1991).
12. *Meyck & Co., Inc. v. Biocraft Laboratories, Inc.*, 874 F.2d 804, 10 U.S.P.Q.2d 1843 (Fed. Cir. 1989).

As is often the case in patent law, gaining patent protection for a natural-based product depends heavily on how the patent claim is drawn.

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Innovative Provisions and Features
of
Biodiversity Prospecting Agreements

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This document focuses on private bioprospecting agreements in light of the Biodiversity Convention's principles of preserving biological diversity, promoting sustainable use, and recognizing the sovereign rights of states over their genetic resources. Examples of contract provisions are provided in an attempt to illuminate a number of legal issues which arise in the commercialization of genetic resources and to be included in a genetic resource agreement in the sequence in which they would generally appear in such an agreement. These provisions include the access to and collection of genetic information, as well as the local knowledge related to it, and the consent agreements under which such knowledge may be acquired.

This legal framework enables developing countries to participate in the fractionation and development of biologically active samples. From a standpoint of optimizing benefits to the host country in the screening process, pioneering contract provisions are provided that pertain to rights in inventorship, ownership of inventions, licensing, and the protection of the intellectual property of local researchers as well as plant users and indigenous peoples. Eventually, this also delineates methods by which the exclusivity that commercial partners typically seek may be reasonably limited, thereby maximizing the present and future values of resources investigated under the agreement.

I. Ownership, Sovereignty, and Control of Genetic Resources

- **Control over Access.** The source country can increase control over the access to their genetic resources by insisting that this international private agreement comply with national collection and research regulations.

"Nothing in this agreement shall abridge the national collection and research regulations of SOURCE COUNTRY. The agreement shall neither abridge the intellectual property rights of the people of SOURCE COUNTRY, under the laws of the United States or any other nation, including SOURCE COUNTRY."

- **Conservation and Sovereignty.** The private partner (e.g. a pharmaceutical corporation, a research institute) should acknowledge the source country's sovereignty in regards to their genetic wealth and the commercial and ecological importance of conserving such wealth in-situ (in its natural ecosystems).

"The government of SOURCE COUNTRY controls the access to and seeks to maintain the sovereignty over their natural resources".

- **Commercial Value.** Each bioprospecting project should preserve the commercial value of the source country's biodiversity by limiting screening to specific species or categories (e.g. angiosperms). The agreement should assure the source country the opportunity to select other commercial partners and devise optimal concession strategies for screening insects, fungi, marine life, and microbes.

"The parties desire to investigate, identify and develop potential medicinal agents from SOURCE COUNTRY angiosperms".

- **Scope of use.** By limiting the time and therapeutic areas for which researchers may utilize extracts, the source country can maintain control over the use of their valuable biodiversity resources. Research collaborators should be made to declare a continuing interest in extracts within a specific delay (e.g. six months of having received them) or relinquish their rights to such extracts.

"The parties desire to investigate marine micro-organisms

as potential sources of novel anticancer drugs"

and

"The PARTNER shall have the sole right to determine which extracts are of continuing interest to it and to determine the methods by which the PARTNER may conduct research, testing and or/further commercialization. The PARTNER, within X months of receipt of an Extract, will declare in good faith whether or not it has a continuing interest in such extract. If PARTNER does not declare that it has a continuing interest in an extract, the remaining provisions under this Agreement cease to apply to that extract."

and

"During any given contract year, the number of extracts declared to be of continued interest shall not exceed X% of the total number of extracts provided by SOURCE COUNTRY during such contract year, unless otherwise agreed upon by the parties."

- **Reporting of Discoveries.** The PARTNER (e.g.pharmaceutical company) should automatically report to the source country the biological activity of all samples. In order to enforce this contract stipulation, the contract should provide for a coding system such that collaborators must report such activity in order to have the botanical identity of extracts illustrating market potential decoded.

"The SOURCE COUNTRY will supply a shipping list to the PARTNER with each shipment of extracts which will include a code for each plant extract. Such code shall contain coded information provided by SOURCE COUNTRY which shall include but not be limited to whether such extract was collected by random collection or on the basis of ethnobotanical considerations, the botanical identification and description of the plant, and location of collection. In the case of extracts collected on the basis of ethnobotanical information, a report summarizing the traditional uses for each such extract will be prepared by the SOURCE COUNTRY.

All such coded information and, in the case of extracts collected on the basis of ethnobotanical consideration, a report summarizing the traditional uses, for a particular extract shall be provided to the PARTNER upon a declaration that such extract is of continuing interest."

II. Compensation

- **License fees and royalties.** All products developed from an extract provided under a bioprospecting agreement should earn a royalty. This includes products covered by patents *as well as* products which do not achieve patent protection. (Trade Secret)
THIS TYPE OF COMPENSATION SHOULD NOT BE LIMITED TO ENDEMIC SPECIES AND SHOULD COVER ALL EXTRACTS FOUND IN THE SOURCE COUNTRY.

"PARTNER agrees to pay a royalty of ---- on the Net Sales Price of any product, hereafter referred to as a "covered product", containing a new chemical entity or prodrug, derivative or analog thereof, isolated by PARTNER from and extract provided by SOURCE COUNTRY."

and

"All licenses granted arising on any invention arising from this collaboration shall contain a clause referring to this agreement and shall indicate that the licensee has been apprised of this agreement."

and

"Should the agent be licensed to a third party for production and/or marketing, the PARTNER will require the successful licensee to negotiate and enter into an agreement(s) with SOURCE COUNTRY. This agreement will address the concern on the part of the SOURCE COUNTRY that it receives, through pertinent agencies, institutions and/or indigenous or local communities receive royalties and other forms of compensation representing no less than X% of the net income received by the PARTNER.

Such terms shall apply equally to instances where the invention is the actual isolated natural product, or where the invention is a product structurally based on the isolated natural product (i.e. where the natural product provides the lead for development of the invention), though the percentage of royalties negotiated may vary, depending upon the relationship of the marketed drug to the originality of the originally isolated natural product, but might not be less than Y% of the net income received by PARTNER."

- **Ethnobotanical premiums.** Products derived from ethnobotanically collected plants should collect higher royalties than those collected randomly. This increase (e.g.: %20) would reflect both the value of such knowledge to the research process and the need to fund programs of development of new drugs that can be accessible by the local communities.
- **Contract Fee.** The parties should agree to negotiate in good faith an upfront contract fee either upon the signing of the contract or thereafter.

"PARTNER agrees to provide SOURCE COUNTRY with an upfront paiement of US\$ X which is to be used for the conservation of SOURCE COUNTRY's natural resources".

and/or

"SOURCE COUNTRY agrees to provide PARTNER with the necessary quantity of sample. The compensation paid to SOURCE COUNTRY by PARTNER for this supply of material is of US\$ X per sample."

III. Technology Transfer and Local Capacity Building

- **Technology Transfer.** The corporate partner can provide the knowledge and/or the financing that will enable the source country to acquire the equipment it needs to increase its in-country capacity to develop extracts of biological specimens. The relationship can also facilitate the transfer of screening and fractionation equipment.

"The PARTNER will collaborate with SOURCE COUNTRY in the development of extraction, chemical isolation and screening expertise to enable organization designated within SOURCE COUNTRY to undertake the evaluation of new natural products and authentication of traditional uses of plant for health care.

The collaboration will take place in laboratories of SOURCE COUNTRY with the financial and technical assistance of PARTNER."

- **Training and Research Exchanges.** The parties can train local scientists in new technologies as well as local people to identify, collect, and extract biological plant material. Research exchanges can be planned under the supervision of the foreign partner.

"PARTNER agrees to invite scientists designated by SOURCE COUNTRY to work in the laboratories of PARTNER or in laboratories using technology which would be useful in furthering work under this agreement. The duration of such visit shall not exceed X months, except by prior agreement between the parties. The designated guest researchers shall be subject to PARTNER's usual guest researcher policy. Salary and other conditions shall be negotiated in good faith."

- **Information and Data Sharing.** Under the agreement, information gathered by the project should be available to the source country, excepting that developed from proprietary screens. Note: in certain cases where detailed agreements have not been negotiated with the SOURCE COUNTRY, the government may want to consider the creation of national regulations that will make permit exports of raw materials subject to the sharing of the data gathered in connection with them.

- **CI/GIS and Species Inventory.** Powerful mapping systems can be used to assist the source country in utilizing the results of a comprehensive inventory toward optimal biodiversity concession strategies which promote conservation.
- **Future Concessions.** The agreement can present previously unavailable concession opportunities by establishing a comprehensive in-country collection of prepared extracts. An initial contract can establish the source country's position in the genetic resource market and increases its visibility with potential partners.
- **Future Supply of Plant Materials.** The source country can supply future commercial raw material needs wherever possible. This creates obvious incentives for conservation and increases the job opportunity in forest communities.

"The PARTNER or its licensees are required to seek as their first source of supply the natural products available from SOURCE COUNTRY."

and

"If SOURCE COUNTRY cannot provide adequate amounts of raw material, the PARTNER and/or its licensees will be required to pay to the SOURCE COUNTRY an amount of money (to be negotiated) to be used to cover expenses associated with the cultivation of medicinal plant species endangered by deforestation and for other appropriate conservation measures. Such terms will also apply to instances where the active agent is prepared by total synthesis".

and

"In the event of large amounts of raw material being required for production, PARTNER will finance the investigation of several production alternatives compatible with the conservation of the biological diversity of SOURCE COUNTRY. Serious consideration should be given to sustainable harvest of the material and involvement of the local populations in the planning and the implementation stages."

IV. Ethnobotanical Research

- **Dual Collection.** A contract can devise several legal innovations to address the intricacies inherent in the simultaneous collection of random and ethnobotanical samples. By utilizing both methods of collection the project will ensure that all plants are tested, yet provide a "jump start" for those plants long known by the forest communities to be medicinally useful.
- **Unprecedented Data Production.** An agreement can develop comparative data on the "hit rates" between random and ethnobotanically collected samples, providing a commercial incentive to preserve, utilize, and compensate the use of such indigenous knowledge.

IV. Using and Conserving Indigenous Knowledge

- **Recognition of Value.** Commercial collaborators should recognize the potential value of indigenous knowledge and in turn the source country can facilitate utilization of this knowledge to enhance drug discovery efforts.

"The local and indigenous people of the SOURCE COUNTRY possess valuable trade secrets, know-how and other intellectual property rights regarding the use of certain of their natural and genetic resources."

and

"Plants will be collected in SOURCE COUNTRY by PARTNER using random collection procedures and on the basis of ethnobotany or similar considerations, and will be transmitted to PARTNER"

- **Informed participation.** All local and indigenous groups participating in the ethnobotanical collection of samples should only do so after they have a complete understanding of the project and given their express consent.

"Collections made by PARTNER which involve the use of ethnobotanical information will be made only after the providers of such information have been informed of the use to which the information will be put and of the rights to potential benefits from such use, and have their written consent to this use."

or

"Should knowledge of the medicinal use of any of the plants by the local communities or traditional healers have been used to guide their collection, the informed permission of the traditional healer or community shall be sought before publication of their information, and proper acknowledgement shall be made of their contribution and proper compensation negotiated."

- **Patent rights for local researcher and shamans.** The agreement should provide for the patenting of all patentable inventions attributable to local and indigenous peoples. In addition, all patenting fees shall be borne by the commercial collaborator.

"All subject inventions made by the employees or agents of either party, including the peoples of SOURCE COUNTRY and its shamans, shall be owned solely by that party. All subject invention jointly made by employees or agents or all peoples and shamans of more than one party shall be jointly owned by the parties who made the subject invention and each such joint owning party shall have and undivided right to practice and/or license such joint invention."

and

"Any party who is the sole owner of a subject invention shall have the first right to prepare, file, prosecute and maintain patent applications and patents throughout the world, in countries of its choice regarding said subject invention at its own expense. The joint owners of a subject invention shall together determine patent filing programs and responsibilities. In situations where PARTNER is joint owner with another party, expenses of patent filing will be borne by PARTNER for all patents in which it expresses and interest. If a party elects not to file, prosecute or maintain such patent application or patents in any other country, it shall promptly notify PARTNER who shall then have the right to prepare file, prosecute and maintain such patent application or patents, at its own expense on behalf of the PARTNER. In such case, the other party shall assist PARTNER, by providing supporting technical information and data by signing all documents necessary for this purpose."

- **Compensation for indigenous knowledge.** Remuneration should follow from the use of indigenous knowledge, both in cases where such knowledge contributes to the development of a commercial product and where such knowledge is requested by the research partners.

"The royalties payable to SOURCE COUNTRY will be calculated by adding an "ethnobotanical premium" of X% to the royalty normally payable for products from randomly harvested samples"

- **Forest Peoples' Fund.** A conservation trust or a similar instrument should be designed to hold funds earmarked for the indigenous groups of the source country. These trusts can disburse royalties earned on any commercial products developed under the agreement.

SUMMARY OF TERMS
COLLABORATION AGREEMENT

INBio-MERCK & CO., INC.

Parties:

Asociación Instituto Nacional de Biodiversidad, a non-profit organization existing under the laws of Costa Rica. ("INBio")

Merck & Co., Inc., a corporation organized under the laws of the State of New Jersey, U.S.A. ("Merck")

Effective Date:

October 1, 1991

Purpose of Agreement:

INBio is interested in collaborating with private industry to create mechanisms to help preserve Costa Rican conservation areas by making them economically viable.

Merck is interested in collaborating with INBio to obtain plant, insect and environmental samples for evaluation for pharmaceutical and agricultural applications.

Obligations of INBio:

INBio agrees to establish facilities for the collection and processing of plant, insect and environmental samples from Costa Rica.

INBio agrees to hire and train an adequate staff to collect and process the samples.

Merck agrees to provide training to INBio staff in Merck facilities.

INBio agrees to supply Merck with a specified number of plant, insect and environmental samples per year over the initial two year period of the Agreement as described in the workplan.

The plant and insect samples will be processed in laboratory facilities which will be established by INBio at the University of Costa Rica.

INBio agrees to maintain appropriate financial records relating to the project and to allow Merck to review such documentation.

Obligations of Merck:

Merck agrees to provide research funding of \$1.0 million during the first two years of the Agreement and to contribute to INBio laboratory equipment and materials needed to establish the processing laboratory at the University of Costa Rica.

Merck agrees to evaluate the samples provided by INBio in proprietary assays for potential activity as human health, animal health and agricultural compounds. Merck agrees to advise INBio of confirmed and reproducible activity that has been identified in an INBio samples.

Merck agrees to assign unique identification numbers to all INBio samples and to maintain an identification system which will allow Merck and INBio to identify all products which may be subject to royalty under the Agreement.

Exclusivity of Arrangement:

INBio agrees that during an initial evaluation period of two years it will not provide to other parties for use in the field of human and animal health agriculture any samples that have been provided to Merck. During the initial evaluation period, INBio is free to offer to other parties samples that have not been requested by Merck. INBio may offer the Merck samples to parties for evaluation outside of Merck's field of interest.

After the initial evaluation period is completed, INBio will be free to offer the samples that have been supplied to Merck to other parties for evaluation for human health, animal health or agricultural uses. With respect to no more than 1% of the total number of samples provided by INBio to Merck, Merck may extend the exclusive evaluation period so long as Merck acts diligently in the evaluation and commercialization of the sample. The exclusive rights will terminate if Merck ceases the program to commercialize products derived from the sample.

INBio may decline to obtain a sample if the samples are impossible to obtain for reasons related to logistics, endangered species concerns or biological concerns.

Merck will provide INBio with written progress reports at least once each year concerning its commercialization activities with respect to a specific sample.

Confidentiality:

During the term of the Agreement and for a seven year period thereafter, the parties agree not to disclose to any third party any confidential information received from the other party under the collaboration.

Either party may publish the results of the research collaboration after providing the other party the opportunity to review the publication.

Invention and Patents:

Inventions made as part of the research collaboration will be owned by Merck and Merck will be responsible for filing appropriate patent applications. INBio will be compensated for its contribution to any invention by a royalty on sales of products, as described in Payments. INBio retains the right to provide samples to third parties for evaluation and commercial development, subject to the limited exclusivity granted to Merck.

Payments:

Merck agrees to pay a royalty to INBio on any human or animal pharmaceutical product of agricultural chemical compound which is isolated initially from or produced by a sample provided to Merck by INBio. The royalty obligation also applies to any products which are derivatives or analogs of such compounds. The royalty obligation applies to chemical compounds derived either from living isolates from environmental samples or from samples of dead tissues.

The royalty rate is confidential business information and will not be disclosed. The royalty rate falls into the range of royalty rates typical for agreements of this kind.

Merck agrees to maintain accurate records which will allow Merck and INBio to identify all products subject to royalty and to enable INBio to confirm the accuracy of Merck's royalty reports.

Indemnification:

Merck agrees to indemnify INBio from any claims arising from the use of the samples, except for any claims resulting from the negligence or other wrongful act of INBio.

Merck agrees to comply with all regulatory and other requirements which apply to the use of the samples.

Term:

The initial term of the Agreement will be two years from the date on which the processing facilities are available for operation.

Three months prior to the termination of the initial term, or any extension after the initial term, the parties shall meet to determine whether to extend the collaboration for an additional one year period. Merck will provide additional funding in an agreed amount to support INBio's work during any extension period.

Termination:

Either party may terminate on ninety days' written notice in the event of a material breach of the contract by the other party.

Either party may terminate if the other party becomes insolvent, makes an assignment for the benefit of creditors, or is the subject of bankruptcy proceedings.

In the vent of termination, the confidentiality obligations and royalty obligations shall remain in effect.

Assignment and sublicensing:

Neither party may assign the Agreement.

Merck may enter into sublicensing Agreements provided that Merck remains liable to INBio for any obligations under the Agreement and that all royalties due to INBio are paid. Merck shall notify INBio of any sublicense which involves the license of INBio samples or INBio confidential information.

Attachment I:

Workplan for the selection, collection and extraction of plant samples.

Attachment II:

Workplan for the selection, collection and processing of insect samples.

Attachment III:

Workplan for the selection, collection and isolation of environmental samples.

Attachment IV:

Annual operation budget.

RIGHTS AGREEMENT

THIS AGREEMENT, effective as of the _____ day of 1993 by and among the Instituto Nacional de Biodiversidad ("INBio"), having offices at Apartado 22, 3100 Santo Domingo, Heredia, Costa Rica, and _____ having offices at _____

WHEREAS, INBio and _____ wish to cooperate in a program of biodiversity prospecting in Costa Rica;

WHEREAS, _____ will provide research support in the form of screening, ingredient isolation, compound characterization, and advice on patents and licensing;

WHEREAS, the parties wish to define their respective shares in any intellectual property rights which might arise out of specific collaboration between _____ and INBio;

NOW THEREFORE, in consideration of the covenants and obligations herein set forth the parties agree as follows:

1. DEFINITIONS.

As used in this Agreement:

- a. Extract means any extract or raw material provided to _____ by INBio from plant and insect resources available in Costa Rica's tropical forests.
- b. Third Party means any party other than INBio or _____
- c. Product means any product, process, substance, compound or mixture or a derivative or analog of any of the foregoing, developed by or for the parties relating in _____

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any manner to the collaboration contemplated by this Agreement, which is isolated from, produced by, derived from or chemically modeled after a substance found in, or otherwise developed, discovered or identified from or as a result of access to, an Extract, including without limitation, chemical compounds, proteins, carbohydrates, genes, DNA, RNA or other genetic materials found in such Extract. The term "Product" shall include any service making use of a Product, such as gene therapy.

- d. Net Royalties means the gross amount of royalties, license fees, profits or any other payments received by a party which result from or arise out of any Product less:
- i) standard published, commercially reasonable, consulting fees actually charged by either party to a Third Party in connection with such Product;
 - ii) the actual cost of materials supplied by either party in connection with such Product;
 - iii) reasonable costs incurred by a party for the patenting of technology relating to such Product; and
 - iv) reasonable costs of marketing such Product incurred by a party.

Such deductions shall not include overhead costs or administrative costs.

e. Confidential Information means all materials, trade secrets or other information disclosed by one party to the other, except as follows:

- i) information which was known to or otherwise in the lawful possession of the receiving party prior to its disclosure to such party or which is developed independently by the receiving party; or
- ii) information which is or thereafter becomes a part of the public domain through no act or omission attributable to employees or agents of the receiving party; or
- iii) information which is hereafter lawfully disclosed to the receiving party by a third party not acquiring the information under an obligation of confidentiality from or through the disclosing party.

2. INBio RESPONSIBILITIES.

INBio shall, in its discretion, supply Extracts to _____ for various research studies in the area of chemical biodiversity prospecting. At INBio's sole discretion, INBio may increase its participation in such studies by performing its own research or by assisting

3. RESPONSIBILITIES.

_____ will use its best efforts) *and operational* to perform research studies for evaluating potential health applications of the Extracts and Products. _____ will keep INBio informed of the progress of

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such studies and will allow INBio to participate in such studies to the extent requested by INBio.

4. ROYALTY DISTRIBUTION.

a. Any Net Royalties received by either party will be divided as follows:

i) % of Net Royalties to INBio

ii) % of Net Royalties to

b. The distribution of Net Royalties shall be paid within thirty (30) days of the end of the calendar quarter in which such Net Royalties were received.

c. INBio intends to use 100% of its portion of Net Royalties and any other compensation payments for the indirect and direct costs of protection and management of Costa Rica's biodiversity.

5. THIRD PARTY PARTICIPATION.

a. Due to INBio's unique concerns regarding the Extracts and the commercialization of the Products, will not make any Extract or any Product available to any Third Party or enter into any transfer agreement or any other arrangement with a Third Party relating to any Extract or Product without prior written approval from INBio.

b. INBio may withhold such approval for any reason, but INBio shall not unreasonably delay in notifying of INBio's decision whether or not to provide such approval.

6. TECHNOLOGY RIGHTS.

- a. The party which employs or controls the inventors of a patentable invention that arises out of or results from an Extract, a Product or the collaboration contemplated by this Agreement shall have the right to file, prosecute and maintain any patent application and patent in its name and at its expense.
- b. Where joint inventorship causes joint ownership between INBio and the parties will mutually agree to designate one party to have responsibility for filing, prosecuting and maintaining patent applications and patents with expenses to be paid as mutually agreed.
- c. Where the party responsible for filing, prosecuting or maintaining a patent application or patent fails or refuses to act, the other party may act to prevent abandonment.
- d. The party filing, prosecuting and/or maintaining the patent application or patent shall keep the other party timely apprised of all substantive communications from Patent Offices.

7. MARKETING AND LICENSING TECHNOLOGY.

- a. Subject to the other terms and conditions of this Agreement, the patent owner(s) shall have the right to market and license the patentable technology.

- b. The party having the right to market and license the patentable technology may permit the other party to market and license the patentable technology.
- c. Regardless of which party markets and licenses the patentable technology, the provisions of this Agreement relating to the sharing of Net Royalties shall be as specified in Section 4.

8. NON-EXCLUSIVITY.

Both parties understand that INBio may alternatively license its chemical biodiversity goods and services, including Extracts and goods and services related to the Extracts, directly to any other entity without any form of involvement by or compensation to

9. TERM AND TERMINATION.

- a. This Agreement shall expire on the fifth anniversary of the date first above written, unless extended by the written agreement of the parties or sooner terminated in accordance with Section 9(b) below.
- b. This Agreement will continue until one or both of the parties terminates this Agreement in the following manner:
 - i) a party may terminate by giving one year's notice in writing; or
 - ii) a non-breaching party may terminate this Agreement for breach of contract after one month written

notice to the breaching party, during which time the breaching party may cure the breach.

- c. If this Agreement is terminated by either or both parties under Section 9(b)(i), the provisions of this Agreement, other than Sections 2 and 3, shall survive.
- d. If this Agreement is terminated by a party pursuant to Section 9(b)(ii), then the provisions of this Agreement, other than Sections 2 and 3, shall survive; provided, however, that the non-breaching party shall be entitled to 100% of the Net Royalties from and after the date of such termination notwithstanding the terms of Section 4 to the contrary.

10. CONFIDENTIALITY.

- a. Neither party shall disclose, divulge or otherwise communicate to any Third Party any Confidential Information received from the other party as a result of this collaboration nor use such Confidential Information for any purpose except pursuant to, as contemplated by, and in order to carry out the terms and objectives of this Agreement.
- b. The Parties further agree that methods and techniques for plant or insect collection and preparation of plant or insect Extract(s), plant or insect names and descriptions, Extract(s), and the terms of this Agreement shall be considered the Confidential Information of INBio. The parties agree to use their

respective best efforts to assure that no unauthorized use or disclosure is made by their staffs to whom access to such information is necessarily granted.

- c. If during the term of this Agreement, either party shall obtain or develop any information regarding hazards associated with Extracts or Products, or substances or compounds contained in any Extract or Product, or any requirements for special handling of such material, it shall promptly inform the other party. Such information shall become Confidential Information and be governed by the terms of this Agreement.
- d. It is recognized that INBio and may wish to publish the results of their collaboration. In order to provide for such publication on mutually acceptable terms, the parties agree that no publication will be made except in accordance with the terms of this Section 10(d). Both parties agree that the form and content of any proposed publication must be approved in writing by both parties (acting in good faith through their respective organizational representatives referred to in Section 11(f) below) prior to its submission for publication and that all publications will be made jointly, unless otherwise agreed upon in writing. All revisions to or modifications of any proposed publication must be approved in writing by both parties prior to actual publication. The submission and subsequent publication

of any proposed publication will be delayed until any intellectual property or confidential information contained in the proposed publication is adequately protected as mutually agreed by both parties.

11. MISCELLANEOUS.

- a. Assignment. This Agreement may not be assigned in whole or in part by either party hereto.
- b. Force Majeure. Neither party shall be liable for delays or failures in performance resulting from acts beyond the reasonable control of such party and the time for performance of such party's obligations shall be extended by a time period equal to the delay caused by such acts. Such acts shall include but not be limited to acts of God, strikes, lockouts, riots, acts of war, epidemics, fire, communication line failures, power failures, earthquakes or other disasters.
- c. Waiver; Delay; Cumulative Remedies. No delay or omission on the part of either party in exercising any rights hereunder shall operate as a waiver of such rights or any other right or remedy. Waiver on any one occasion shall not be construed as a bar to or waiver of any right or remedy on any future occasion. All of the rights and remedies of either party hereunder, shall be cumulative but may be exercised singularly or concurrently.

- d. Independent Contractors. This Agreement does not constitute and shall not be construed as constituting a partnership or joint venture between INBio and The relationship between INBio and under this Agreement is solely that of independent contractors. Neither party shall have any right to bind the other or incur obligations on the other's behalf without the other's prior written consent in each instance.
- e. Governing Law. This Agreement shall be governed by and construed in accordance with the laws of the State of
- f. Notices. The date of any notice given hereunder shall be the date on which such notice is received rather than the date on which it is sent. Notices and other communications under this Agreement shall be in writing and shall be sent by telecopier, reputable overnight delivery service or registered mail to the parties as follows:

If to INBio: Instituto Nacional de Biodiversidad
 Attn: Dr. Ana Sittenfeld
 Director, Biodiversity Prospecting Division
 Apartado 22
 3100 Santo Domingo, Heredia
 Costa Rica

If to

or to such other addresses as either party to this Agreement may from time to time furnish to the other.

- g. Complete Agreement. The provisions contained herein and in any Exhibits to this Agreement set forth the entire agreement between the parties with respect to the subject matter hereof and supersede all previous communications, representations or agreements, whether oral or written, with respect to the subject matter hereof, and no addition to or modification of this Agreement or such other documents and instruments shall be binding upon either party unless reduced to writing and duly executed by both parties hereto.
- h. Severability. Each of the provisions set forth in this Agreement, and each part thereof, is and shall be deemed to be severable. If any part of this Agreement shall be deemed to be invalid, illegal or unenforceable, the remaining provisions or part of the Agreement shall remain in full force and effect.
- i. Headings. The headings of the sections and subsections of this Agreement have been added for convenience only and shall not be deemed to be a part of this Agreement.

IN WITNESS WHEREOF, this Agreement has been duly executed by
the parties as of the date first above written.

INSTITUTO NACIONAL DE
BIODIVERSIDAD

By: _____

By: _____

Title: _____

Title: _____

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SECTION 7

PARTICIPANT CONTRIBUTIONS TO THE WORKSHOP

SECTION 7: WORKSHOP PARTICIPANTS' CONTRIBUTIONS

Introduction:

At the bioprospecting workshop, participants were invited to give short talks on biodiversity property rights issues and bioprospecting projects, including inventories, that are currently being conducted in their home countries. The papers which follow are based on these talks and have been presented here to provide the reader with general information regarding the four countries participating in this workshop.

Contents: Section 7

- Approaches to Domestication of *Ancistrocladus Korupensis*, A Cameroonian plant of possible medicinal value. By Johnson G. Jato
- The Role of Various Stakeholders in the Development and Conservation of Biological Resources in Cameroon. By Thomas Tata-Fofung
- The Biodiversity of Cameroonian Flora. By Dr. Benoit Satabie
- Evolving National Policy Debate on Bioprospecting in Ghana. By Edwin Barnes
- Inventory Needs in Ghana. By A.A. Oteng-Yeboah
- Perspectives for a Biodiversity Prospecting Program in Madagascar. By Jean I.M. Rajaonarivony
- U.S. Perspectives on the Convention on Biological Diversity. By Robert C. Szaro

APPROACHES TO DOMESTICATION OF ANCISTROCLADUS KORUPENSIS , A CAMEROONIAN PLANT OF POSSIBLE MEDICINAL VALUE

by

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Vice Dean Faculty of Medicine and Biomedical Sciences
and
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INTRODUCTION

When the interest in the michellamines increased because of their activity against HIV 1 and 2 as well as the antimalarial activity of the korupensamines, it became evident that it would be necessary at some stage to have large amounts of *Ancistrocladus korupensis*, the source plant of these compounds. A survey of the Korup National Park indicated that the distribution of this plant was in the order of two plants per hectare. It was very clear from the results of this survey that this species is very rare and that to get sufficient quantities of leaves for industrial scale preparation of these alkaloids, it would be necessary to cultivate it. Studies to find out whether or not the plant could be cultivated were envisaged. (Slide 1 michellamine B and slide 2 *A. korupensis*).

CULTIVATION FROM WILDINGS

The first thought was to grow the plant from seeds, but as there were no seeds then, we did not know whether or not this plant had viable seeds. While waiting to see if there would be any seeds in the course of the year we tried to answer another question, namely whether the liana would grow in a habitat, different from the natural one. To find this out we dug some young seedlings from the forest (wildings) in Mundemba and tried them in Yaounde, where they would be easy to monitor. As this was in February and consequently the dry season, we had to water them daily. Whereas the growth was not very spectacular they looked fresh until

the rains came in April. One thing appeared certain, namely that *A. korupensis* could grow away from Korup, the natural habitat. This was useful information because this did not exist before this time. However, we were still not satisfied that we had no information about seeds the whole of that year.

CULTIVATION FROM SEEDS

In March of 1993, one of our technicians found some inflorescence, a sure hope that seeds were likely to come later in the season. (Slide 3- inflorescence). These structures were also important in that they enabled the botanists to continue the description of the new species. By June we already had many seeds, an opportunity to try what we had wanted to do from the year before. We had well over 99% germination of the seeds in less than two weeks, not only in Korup, but in Yaounde as well. We had in this way found that *A. korupensis*, until now a wild vine, could be grown from seeds even in places far from the normal habitat and without any special treatment of the seeds.

Whereas this success with cultivation from seeds was reassuring that the liana could be domesticated, cultivation on an industrial scale was still going to be a problem. As we had noticed that seeds were produced only every other year, we could therefore not expect to plant a crop annually. On the other hand, we realized that one seed could give only one plant. This was insufficient for large scale industrial production of *A. korupensis* leaves. Our next desire was to try vegetative propagation, since one branch could give us about 6 cuttings and consequently about half a dozen seedlings.

VEGETATIVE PROPAGATION

We were aware that vegetative propagation was a more technical procedure and that we would need expert help. We therefore consulted forestry technicians working in the Yaounde nursery of the National Organization for the Development of forests (ONADEF). We worked

with them to make cuttings with the right leaf area, dipped the end of each one in rooting hormones planted in top black soil and watered these daily in the open air for 3 months. There were no roots formed even after that long period. We repeated the same experiments in the shade. Yet, there was no rooting. We used the same procedure for certain ornamental shrubs and they rooted in less than one month in the same hormone, used in the same way.

We then consulted certain foresters, who were using vegetative propagation for their research on timber trees. They told us that they had had similar setbacks with some of their cuttings and finally solved their problem with the help of nonmist high humidity propagators. (Slide 4 Propagators). By applying the same technique to *A. korupensis*, we obtained rooting in about a month.

This was a valuable achievement. For the first time ever, we had succeeded in producing *A. korupensis* by vegetative propagation. We also found out that for this technique to work for *A. korupensis* we needed high humidity of about 80% for the period that the cuttings were being made to root.

Even with the multiplying effect that we had succeeded in having from cuttings we still felt the need to go further. We saw the possibility of producing many plants from a small piece of living tissue. This we knew could be realized by cell culture.

CELL CULTURE

We have in Cameroon a very well equipped plant tissue culture laboratory - the Jay P. Johnson Biotechnology Laboratory. It had been very successfully used to produce food crops, such as cocoyams and plantains by plant tissue culture. When we contacted the researcher in charge of the laboratory he was sorry to inform us that the laboratory had been closed indefinitely for two reasons: first because there were no materials to work with and second and worse still the workers were on strike because they had many months of unpaid salary. These difficulties both came from the economic crisis through which the Ministry of Scientific

Research was going.

We were obliged to look for collaborators outside the country. We succeeded in linking up with Phyton Catalytic in Ithaca, New York. They provided the expertise, the material and the equipment, but the work had to be done in their laboratory, where they were doing some very successful work on taxol. I would bring my material and we would work together. The Manager and Chief Executive Officer signed papers offering joint publications with me and royalties for Cameroon with the promise of eventually setting up in Cameroon a pilot plant for long term storage of living plant tissue, like what they had in Ithaca. We worked together last December and January to produce callus from which Michellamine B as well as korupensamines were isolated. Unlike in the case of taxol, we encountered some slight contamination, which we were in the process of eliminating at our end in Cameroon during the initial preparation of the samples. As from January ending the work was stopped because the Follow Up Committee for the Exploitation and Conservation of *Ancistrocladus korupensis* is working on a suitable agreement with NCI as the Economic Adviser of the Prime Minister will indicate in his paper.

CONCLUSIONS AND RECOMMENDATIONS

The rare Cameroonian liana, *Ancistrocladus korupensis*, can be grown from seeds without any particular prior treatment of the seeds. It can be vegetatively propagated from cuttings, but for rooting to take place high humidity is required. The plant can be grown in regions of Cameroon that are different ecologically different from the usual habitat. Cell culture is also a feasible method of propagation, but the tissue may need to receive prior treatment to prevent bacterial and fungal contamination.

ACKNOWLEDGEMENT

The author would like to acknowledge the following people for their essential contributions to the *A. korupensis* project: James E. Simon, Paul Symonds, Duncan Thomas, Mario R. Morales, Zacharie Tchoundjeu, Christopher Njoya, Roy Gereau, Ben Alkire, Emmanuel Jato and Tom McCloud.

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THE ROLE OF VARIOUS STAKEHOLDERS IN THE DEVELOPMENT AND CONSERVATION OF BIOLOGICAL RESOURCES IN CAMEROON

by

Thomas Tata-Fofung

1. Cameroon's biodiversity is found in the ecological zones of:

- Coastal Marines
- Mangroves
- Forests
- Savannahs
- Coastal Mountains
- Woodlands
- Rivers
- Lakes
- Sudano-Sahel
- etc.

Within and around these ecological zones exist local communities made up of villagers, farmers, fisherfolk, forest dwellers, traditional healers and more. These local communities and all other stakeholders depend on the natural resources from biodiversity for livelihood, whether from:

- Agriculture
- Medicine, or
- Industry, etc.

2. THE PROBLEM

2.1 Degradation of the environment is continuing, and its many causes are leading to the loss of vegetative cover and loss of biodiversity.

Result/Example (1990):

- Cameroon is said to have already lost 59% of its wildlife habitats.
- Of 220.000 km² of original forest cover, 164.000 km² are remaining with 60.000 km² secondary forests.
- The yearly deforestation rate is estimated at 2000 km² per year.

2.2 Inadequate knowledge

2.3 Institutions and financial resources are inadequate.

2.4 Slowness in decision-making - policy, legislation, etc.

3. BIODIVERSITY DEVELOPMENT AND CONSERVATION

3.1 Environmental degradation leads to depletion of biodiversity caused by:

- AFFLUENCE IN DEVELOPED COUNTRIES
- POVERTY IN DEVELOPING COUNTRIES

Therefore it is a world concern.

3.2 Solution

- SUSTAINABLE DEVELOPMENT AND CONSERVATION OF BIOLOGICAL RESOURCES

3.3 To attain sustainable development, strategies, goals, objectives and principles must be set up.

Among underlying principles most critical for sustainable biological resources development are:

- participation;
- sustainable development of natural renewable resources should be an integral part of government policy articulated through planned programs and projects for effective implementation;
- based on sound scientific knowledge which should guide policy;
- considered and investment with costs/benefits shared between stakeholders; and
- increased awareness.

4. THE STAKEHOLDERS AND THEIR ROLES

Stakeholders are those who have an interest and thus concern for something because of perception and/or claim of ownership, user-rights, beneficiary or simply advisory obligations.

Thus, local communities, economic interest groups, NGOs, scientific and recreational tourists, government and the international community are all stakeholders of biological resources. Their roles must be based on participatory approaches, i.e., working together and sharing responsibility for outcomes or results.

4.1 LOCAL COMMUNITIES ARE MADE UP OF PEOPLE WHO:

- directly depend on biological resources for survival;
- usually would live in harmony with nature;
- are stewards of the land with ITK that can provide some keys to the sustainable management of bioresources;

BUT

- are usually accused as degraders of the environment

HOWEVER, THE PROBLEM IS:

- they are poor;
- they lack both support and economic incentives; and
- are usually coping with inadequate or inappropriate technology.

THE RESULT IS THAT:

- demographic pressure and poverty push them into:
 - * marginal land which is too dry, too steep and lacking in nutrients;
 - * cutting down forests, mangroves etc. for more farm land, fuel wood, building etc. e.g. savannahs and Sudano-Sahel regions.

SOLUTION

- Encourage use of ITK;
- Encourage participation;
- Organize/create groups or strengthen existing ones;

- Foster alternative technology that is adequate, appropriate and adaptable;
- Foster local community management capabilities and responsibilities and make them partners in development so that they can effectively play their role in the development and conservation of bioresources.

4.2 ECONOMIC INTEREST GROUPS

- 4.2.1. Timber exploiters, commercial fuel wood exploiters, exploiters of secondary forest products.
- 4.2.2. The agroindustries.
- 4.2.3. The pharmaceutical industries.
- 4.2.4. The mining industry including quarries.
- 4.2.5. The public utilities industries - water, electricity.

4.3 The NGOs

- local
- international

4.4 The scientific and recreational tourists.

4.5 The Government.

4.5.1. The role includes the following activities:

- Assuring welfare;
- Assuring food security, environmental security;
- Providing policy, administrative and legal framework;
- Providing enabling political, social, economic, and financial environment.

4.5.2. What has been done so far:

- Creation of MINEF in 1992 just before Rio;
- New forestry policy;
- New forestry, wildlife and fisheries law;
- Tropical forest action plan;

- Territorial zoning plan to partition ecological zones that will define the potentials and constraints to enable the planning for their utilization;
- National programme for the management of the environment;
- Pilot project for the conservation of biodiversity GOC/WB/GEF;
- Party to subregional, regional and international conventions.

5. CONDITIONS FOR EFFECTIVE ROLE PLAY

- Enabling environment
- Institutional requirements
- Adequate management systems
- The reorientation of technologies

6. THE ROLE OF BDCP-CAMEROON

- Join hands with all stakeholders.

THE BIODIVERSITY OF CAMEROONIAN FLORA

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INTRODUCTION

Cameroon is generally presented as a Microcosmos of tropical Africa, so to say a synthesis of Africa or even a miniature Africa.

This assertion is more particularly true in matters of flora and phytogeography, because the landscapes and vegetation of Cameroon represent a rich condensation of those of tropical Africa with great dense forests to the south, savannahs in the centre, steppes and thorny vegetations in the north and mountains here and there, particularly in the western ridge.(backbone?)

Such natural dispositions cannot but augur a higher potential for the biological diversity of Cameroon. The objective of the present communication is, thus, to put in evidence the biodiversity of the rich Cameroonian flora, essentially on the basis of the work done at the National Herbarium. The collection of the Botanical Garden at LIMBE, although susceptible to modification of the present data in an augmentative sense, is of regional interest and possesses, specially, almost all its doubles at the National Herbarium at YAOUNDE.

1- SOME NUMERIC DATA ON THE CAMEROONIAN FLORA

On planet Earth, some 350.000 species, of which almost 55.000 in Africa, of so called superior plants including essentially trees, shrubs, vines and herbs, occupy the ground, leaving aside the whole strange and singular world of marine Algae, Mushrooms, Lichen and Mosses.

Among these 350.000 species, at least 7.500 or even 8.000 are present in Cameroon, i.e. about one plant per each forty five. The percentage of these 8.000 species represented in the rich collection of the National Herbarium, which already gathers close to 70.000 botanical samples from the national floral heritage, is present 90%, with among other things, a Carpothecary of more than 500 fruits and grains, dried or on alcohol, an Anthothecary of more than a hundred flowers in preserving liquid and a Palynotheary of some 1.200 microscope plates mounted in grains of pollen.

At the present time, the National Herbarium includes in actual fact 1760 varieties out of an estimated total of 1.800 and 232 families of very unequal importance. In effect, the present statistics of Flora (books) and the recently effected

counts at the National Herbarium present the Leguminous plants as the largest group with a total of some 170 varieties and 640 species. Nevertheless, taken individually, the most important families are the Rubiaceae: 110 varieties and 520 species, the Poaceae: 125 varieties and 433 species, the Fabaceae: 90 varieties and 420 species, the Orchidaceae: 55 varieties and 355 species, the Euphorbiaceae and the Asteraceae: 80 varieties respectively and 250 species each, etc...

Of the 232 families and 1.760 varieties which the collection of the National Herbarium has, 109 families, 609 varieties and 2.180 species have already been studied, described and indexed in detail, with 17.220 botanical samples quoted in 35 volumes of the Flore du Cameroun (Flora of Cameroon) (Flora with a capital "F" because it is a basic scientific publication in the form of a Dictionary, giving a description of all the plants of the country).

From these statistics, it appears that almost all of the families and more than 3/4 of the varieties of plants existing in the country are already present in the collection of the National Herbarium. so that almost half of the families (48%), more than 1/3 of the varieties (35%) and a little over 1/4 of the species (27%) of this flora are described and catalogued in this dictionary, which is the Flore du Cameroun up to this date. To that is added a phytogeographical map at a scale of 1/500 000 by LETOUZEY (1986), giving the synthesis of the different types of vegetation of Cameroon.

In support of the potential riches of the Cameroonian flora, the "Bulletin d'Information de l'Union Internationale de la Conservation de la Nature (IUCN, 1979) reports that in the only reservation at Douala-Edá, covering a surface of 160.000 hectares, about 250 species of plants have been recorded.

Likewise, in the Nation Parc of Korup, which covers some 125.000 ha, the same review indicates that almost 500 species of plants have been identified. With this record cipher, this reservation is reputed to be florally the richest of all the forests studied in Africa. This reputation is actually heightened by the recent discovery in this place, by Dr. Thomas (1993) of a species of ANCISTROCLADACEAE: *Ancistrocalus korupensis*, a kind of magical plant, endemic to this region, evaluated very highly and very promising in the investigation of cancers in general and of AIDS in particular.

At a continental level, at the heart of the guinea-congo forest flora, the cameroonian biodiversity richness is equally illustrated by this study of Aubréville (1968) of the flora of the Césalpiniaceae which indicates that the flora of cameroon-gabon (Central Territory) in general and the cameroonian flora in particular, is by far the richest, with 62 varieties and 175 species against 42 varieties and 81 species of the western flora (from Sierra Leone to Bénin) and 48 varieties including 100 species

for the flora of the Congo (Eastern Territory).

II- SOME ENDEMICS OF CAMEROON

In this very diverse scope of plants existing in Cameroon, some of them are specifically from there, being unknown in other countries, even neighboring countries. These are the endemic species.

So, of 2.180 species described and indexed into 109 families, more than 160 species are counted which are characteristic of Cameroon and belong to diverse families, of which the richest ones are by order of importance: Orchidaceae: 30, Podostemaceae: 18, Lauraceae: 17, Melastomataceae: 14, Cesalpiniaceae: 11.

The region of Mount Cameroon in particular, and the Western mountains in general, which have served as a "refuge" to many species during the periods of climatic changes, are the most interesting regions in phenomena of endemisms. Thus, of the Orchids for example, 113 species regrouped into 32 varieties, or 34% of the cameroonian species and 62% of the varieties, are found there.

On the other hand, among these 2.180 species already indexed in the Flore du Cameroun, only 162 have been found in one single country other than Cameroon, specially in Gabon with 87. followed by Nigeria: 39 and Equatorial Guinea (Bioko): 16.

III- CONCLUSION

So it appears clearly that Cameroon possesses and benefits of a rich flora, for which the areas of use are extremely diverse. It deserves to be qualified as the "Microcosmos of Africa", and by virtue of that title constitutes the choice territory for the studies and the investigations on biodiversity.

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**A PRACTICAL WORKSHOP ON BIODIVERSITY
PROSPECTING FOR CAMEROON, MADAGASCAR AND GHANA**

APRIL 26 - MAY 3, 1995

COUNTRY PRESENTATION:

**"EVOLVING NATIONAL POLICY DEBATE
ON BIOPROSPECTING IN GHANA"**

By: Edwin Barnes

MINISTRY OF ENVIRONMENT, SCIENCE AND TECHNOLOGY

GHANA

**INBIO, COSTA RICA
MAY 2, 1995**

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NATIONAL DEBATE ON BIOPROSPECTING POLICY IN GHANA

Introduction

Bioprospecting has not received much attention in Ghana as a major field of activity even though a number of activities have been taking place in the country by individuals and institutions which come under the broad concept.

Having ratified the Convention on Biological Diversity, Ghana through the Ministry of Environment, Science and Technology, is now looking at issues relating to the country's biodiversity in a more holistic manner. The first stage of this is a Biological Diversity Country Study which has been initiated by the Ministry. This should provide the country with the relevant information on the state of the country's biological diversity, legislation and institutional arrangements, among other things. The Ministry would subsequently develop strategies and action programmes for the sustainable utilisation and conservation of the country's biological resources.

A policy relating to biosprospecting will be one of the outcomes of the process currently in progress. Issues that will be of interest in the proposed policy document will include

- ownership of biological resources;
- legislation, including contracting arrangements;
- capacity building; and
- international (global) considerations.

Ownership Of Biological Resources

Land ownership constitutes one of the major constraints with respect to the prospecting of Ghana's biological resources. Lands, though vested in the state, are owned either by individuals, traditional rulers or the government itself. In many instances, there are conflicts over ownership of land and this has its effect on activities that can take place in the land as well as the resources on it.

With respect to minerals, these are vested in the State regardless of ownership of the land. Prospective mineral prospectors and/or extractors need permits before they can undertake these activities. Similar arrangements relate to the felling of timber. There are legislations covering these arrangements.

Unfortunately, owing to the lack of appreciation about the economic value of other biological resources, there are no such laws for their management. Individual land owners thus literally own the resources on their land and use them as they seem fit.

Owing to the importance currently associated with biological resources, especially with respect to their prospecting, the thinking is that there should initially be national sovereignty over these resources in order to discourage industries in the developed countries from having free access to these resources with the connivance of a few individuals for their personal gain. The state should then enter into arrangements with interested agencies to ensure that communities, in which the resources are found, derive some benefits from these resources. This should help in the conservation of the resources and the putting in place of appropriate mechanisms for their utilisation in a sustainable manner.

Legislation

The successful organisation of bioprospecting activities in the country will depend on the existence of a legal framework to help in the management of the activities. The legislation should cover such issues as

- role of the state;
- ownership of the biological resources;
- rights and obligations of the indigenous population;
- access to the biological resources;
- rights and obligations of the collector with respect to conduct, liability and payments

Capacity Building

For bioprospecting to be successfully conducted in the country, Ghana will need to develop the capacity - both institutional and human - to appreciate better the importance and value of the resources. Capacity will also need to be developed so that Ghana can appreciate better the technologies associated with adding value to the biological resources.

The areas for which capacity will need to be developed include

- research institutions and the Universities (scientists, legal personnel, sociologists, management personnel, etc);
- indigenous communities;
- non-governmental organisations;
- private sector.

The capacity building should help Ghana to derive optimum benefits from her biological resources.

International (global) Considerations

As a member of the global community, Ghana supports all efforts at the international level towards the sustainable management of the world's biological resources. For instance, Ghana believes in the Convention on Biological Diversity as being the bedrock for ensuring that the world's biological diversity is used for the benefit of mankind.

Ghana will thus forge partnerships (North-South and South-South) for the exchange of information on biological diversity programmes and systems.

Ghana will co-operate with other countries in ensuring that trade in biological diversity is taking care of in the portfolio at the World Trade Organisation.

Conclusion

Ghana believes that it is important for bioprospecting to be considered as a critical activity to support its various economic and trade policies based on her biological resources. Present legislation calls for the preparation of EIAs for all investment programmes in the country. This should ensure that such investments which will depend on the use of the country's biological resources have included in them programmes that will lead to the sustainable use of the resources. The EIA also calls for conservation programmes. The use of the EIA, however, will not take into account all aspects of bioprospecting. As indicated earlier, the Biological Diversity Country Study should provide the basis for evolving a Bioprospecting Policy for the country.

The experiences of countries such as Costa Rica will, it is hoped, help Ghana in this search.

INVENTORY NEEDS IN GHANA

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INTRODUCTION

Three different groups of authority with varied objectives assume responsibility for the protection of Ghana's wildlands.

The Game and Wildlife Department (GWD) of Ghana practices the IUCN (1990) categories of legal protected areas system; with the main objective of protecting wildlife (mainly faunal) in the different ecological zones of the country. The distribution of the protected area reflects this. Every ecological zone is represented. The protected areas are classified as Strict Nature Reserves, National Parks, Wildlife Sanctuaries, Game Production Reserves, Biosphere Reserves, World Heritage sites and Ramsar Wetland sites according to the level of human activity permitted. These areas are strictly enforced by GWD personnel.

The Forestry Department (FD) of Ghana practices the rotation or felling cycle reservation. A number of forest reserves have been created in the forest areas of the south purely for the purpose for timber production and exploitation. The FD is expected to authorise and supervise the category of felling by the concessionaires, but in many cases, the latter is left to do what it pleases. The result is the felling of undersized trees; and the conversion of parts of the forest reserves into food or cash crop plantations.

The traditional authorities practice the concept of traditional groves for the protection of the areas which they consider sacred either as abode of the spirits of their dead ancestors or the sacred totem or the tabooed organism (plant or animal) of the community. Usually such groves are located close to the community and their protection is enforced by taboos and local traditions. These groves are scattered throughout the country, in each ecological zone, and they all have similar administrative structures which normally involve a spiritual head (usually a fetish priest) and a council of elders and linguists who perform rituals.

THE EXTENT OF INVENTORYING ACTIVITIES OF THE GHANAIAN WILDLANDS

The level of inventorial activities in the Ghanaian wildlands is still in its infancy. Inventorial activities have largely been concentrated at the forest reserves administered by the Forestry Department, purely for the purpose of stock assessment of timber trees (Ghartey 1989).

It was only recently that the study was extended to cover all trees, whether or not they are of any economic value (Hawthorne 1990). This particular decision was informed as a result of recent interest in lesser known trees for timber and lumber trade (Oteng-Yeboah 1994a). Currently, the inventory has even been extended to cover the ground flora, including the herbaceous flora (Hawthorne personal communication).

The Game and Wildlife Department has also initiated inventorial studies in their protected areas. Thus in addition to looking at the different animal species and their population densities in the parks and protected areas, some form of floral inventories are also being undertaken. The level of the floral inventories is meant to establish vegetation associations and the food sources of the animals in the protected areas.

In a rather rare situation, perhaps because it involved Ramsar Wetland sites which permit sustainable use of resources in the site, an inventory of the plants of folkloric and ethnobotanical uses made in addition to the general species inventory (Oteng-Yeboah 1994b).

Inventory activities in the traditional groves had been non-existent until recently. This is because of the difficulties involved in obtaining permission to enter the groves and the attendant restrictions placed on the researcher.

The recent efforts of the UNESCO-CIPSEG project (Cooperative Integrated Project on Savanna Ecosystems of Ghana) has enabled a comprehensive inventory of three traditional groves in the northern Ghana Guinea Savanna to be made (Oteng-Yeboah 1993).

Considering that there are over 1500 traditional groves in Ghana (Tuffour 1993), this is not so much a big deal, even though it is a big start.

PERTINENT INVENTORIAL ISSUES

From above, it is clear that inventorial work in Ghana has lagged behind.

The fact is that effective bioprospecting adventures must naturally be based on a proper inventory; and that various levels of bioprospecting initiatives are already in existence involving private and institutional collections either for local or international level academic and or entrepreneurial activity, the

latter level at which no national controls are available; and that much of Ghana's pristine forests are rapidly being converted into other land use options, there is an urgent need to know what we have (Oteng-Yeboah 1992). This need has never been felt till now when every country is now occupied with initiatives to safeguard its biological resources.

To know what we have involves the activities of taxonomists. There are so few of this kind of specialist in the country and that constitutes the taxonomic impediment in the knowledge of the country's biodiversity, which incidentally happens to be the case in the whole of Africa, south of the Sahara, excluding South Africa (Oteng-Yeboah 1993).

This impediment is real and will remain with us if the appropriate measures are not made to remove it.

One obvious solution is the creation of job outlets for people with that kind of training. Undergraduate and graduate students had previously shunned the discipline because of the lack of job opportunities (Oteng-Yeboah 1991).

Since inventory work involves voucher preparations which must be properly curated, the need to develop national depository centres is imperative.

Such centres as Fungal Collection centre, Bacterial and yeast collection centre, National Herbarium, Museum and Botanical Garden are urgently needed to serve as the country's ex situ reference points.

The development of these national depository centres will create jobs for specialist needs in the systematics and taxonomy of Ghanaian fungi, bacteria and yeast which constitute the microbiological diversity; and in the systematics and taxonomy of higher plants (including algae and bryophytes) and animals (both vertebrate and invertebrate).

The singular decision to create national depositories, which will appoint specialists for various curatorial and other research needs on the Ghanaian biodiversity including inventories, is considered as the answer to taxonomic impediment which has kept the knowledge of the indigenous African biodiversity at this very low level.

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PERSPECTIVES FOR A BIODIVERSITY PROSPECTING PROGRAM IN MADAGASCAR

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It is believed that eighty percent of the world's population still relies on medicinal plants for its primary health care. This is mainly due to the cost of medicines developed from ethical pharmacology, and the inability of many countries to implement a national health care program. However, with the rapid disappearance of tropical forests, policy makers and decision makers should be aware that traditional knowledge is also disappearing. Three years after the "Rio Convention" it now is the appropriate time to really ask the question about "What National Policy to adopt in Madagascar for Biodiversity Prospecting?".

I. OPPORTUNITIES FOR BIODIVERSITY PROSPECTING PROGRAMS

The problem of environmental destruction is acute in Madagascar. However, although known for having one of the richest of the world's biodiversity, species are being lost rather than chemically examined. Many organisms have yet to be discovered in the remaining rainforest. Beside plants, interest should also be focused on marine macro-organisms, insects, microbes and fungi. Worldwide, many major pharmaceutical companies (Merck and Co., Monsanto, Abbott Laboratories, Shaman Pharmaceuticals) and public institutions (National Cancer Institute, Strathclyde Institute for Drug Research, etc.) are implementing screening programs. Indeed, with the progress of biotechnology, several bioassay techniques become available. For instance, by using new molecular techniques (such as cloning of genes for receptor molecules, the usual targets for drugs on the surface of cells), a laboratory can now screen thousands of samples per week.

Thus Madagascar needs to adopt a proper national policy to benefit from the collection of its genetic resources. A new type of relationship which could provide benefits to local people, communities and proper agencies, such as the "Centre National d'Application des Recherches Pharmaceutiques (CNARP)", should be developed with the pharmaceutical industry. Yet the implementation of such programs calls for concerted action between several institutions (ministries, NGOs, private industry and research centers).

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II. EXISTING INSTITUTIONS AND FUTURE POTENTIAL

What kind of potential does Madagascar possess for the implementation of a National Biodiversity Prospecting Program?

Four Ministries, namely the "Ministere de la Recherche Appliquée au Developpement", "Ministere de l'Enseignement Superieur", "Ministere de l'Agriculture (Department des Eaux et Forêts)", and the "Ministere de l'Environnement" have already acquired a large amount of data. How to amass this information is the main priority. The same is true for non-governmental organizations (NGOs) such as the "Office National de l'Environnement (ONE)", "Association Nationale pour la Gestion des Aires Protégées (ANGAP)", and the "Association Nationale pour l'Environnement (ANAE)". The NGOs play a major role in the biodiversity component of the Environmental Program funded by the World Bank. Notice that the primary forests which are the main target for chemical prospecting are often confined within the reserve areas.

To a larger or lesser extent, international organizations such as the "Office de Recherches Scientifique des Territoires d'Outre-Mer (ORSTOM-France)", the Missouri Botanical Garden (MBG, USA) the World Wildlife Fund (WWF) and Conservation International (CI) have also undertaken inventory or integrated conservation programs in Madagascar. Finally, public institutions issued from the "Ministere de la Recherche Appliquée au Developpement", the Centre National de Recherche sur l'Environnement (CNRE)", and especially the "Centre National d'Application des Recherches Pharmaceutiques (CNARP)" are the pioneers for biodiversity prospecting. Of particular interest are the results obtained by CNARP since its creation. Using a multidisciplinary approach: ethnobotany, chemistry, pharmacodynamics, pharmacy and clinical experimentation, the Centre is able to produce medicines under galenic forms (phytopharmacy). A wound healing cream is already being produced on a pilot scale for the local market. It is this type of effort which needs to be supported.

III. CONCLUDING REMARKS

Madagascar has the potential for a Biodiversity Prospecting Program. In fact, what beclouds the implementation of a national policy is the "lack of coordination". Inventory data should be gathered, national databases should be created and efforts should be undertaken to monitor all research on any Malagasy wild species. In addition, Madagascar needs to ratify the "Rio Convention". It is expected that without this legal framework, the country will continue to lose from the apparent, prevailing, "free of charge" exploitation of its genetic resources.

The scenario with Madagascar's Vinca rosa, or Rosy Periwinkle, from which the world's most powerful anti-cancer agents Vincristine and Vinblastine are extracted, will be repeated again. Both drugs reportedly account for around one million dollars in sales each year with no benefit shared with the country of origin.

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The National Center for the Application of Pharmaceutical Research is an institution having both industrial and commercial character. Its main objective is to produce medicine at a low cost from medicinal plants and to provide technical assistance to the private sector essential oils industry - quality control, extraction etc.

Structure: Board of Trustees
Administration
Research Departments

I. Botany Department

- Ethnobotany: Collect data on traditional medicine and other useful plants
- Classification: Botanical identification
- Applied Research: In vitro culture, plant dehydration using a solar dryer and grinding mills

II. Chemistry Department

- Medicinal and Aromatic Plants: Preparation of crude extracts and active principle isolation
- Quality Control Laboratory: Equipped with a G.C., an HPLC, UV, and Spectrophotometer, etc.
- Determination of optimal conditions for extraction of medicinal plants and essential oils on an industrial scale

III. Pharmacology Department

- Bioassays: In vitro tests and in vivo tests on isolated organs, bio-guided fractionation
- Toxicology: Research on secondary effects
- Microbiology

IV. Pharmacy Department

- Preservation, improvement of organolipids, quality and conservation of active extracts
- Galenic formulation of medicinal plant extracts

V. Clinical experimentation

- Phase I and II: Determination of the toxicity and the effectiveness of medicines or the active extracts
- Phase III and IV: Comparison of medicines or the active extracts to a standard
- Toxicology

Programs:

- Anti-diarrhea
- Anti-bacteria
- Anti-parasite
- Anti-malaria

Essential Oils produced

- Niaouli - *Melaleuca leucadendron* L.
- Eucalyptus - *Eucalyptus globulus* L.
- Clove tree - *Syzygium aromaticum*
- Camphor tree - *Cinnamomum camphora*
- Cinnamon - *Cinnamomum zylaricum*
- Clove nect - *Ravensara aromatica*
- Rosemary - *Rosmarinus officinalis*
- Ginger - *Zingiber officinale* R.
- Citronella - *Cymbopogon citratus*

U.S. Perspectives on the Convention on Biological Diversity¹

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Introduction

Efforts to develop the framework Convention on Biological Diversity were launched by the United Nations Environment Programme (UNEP) in May 1989 when the Governing Council of the UNEP unanimously adopted a resolution introduced by the United States to begin negotiations on an international convention to conserve biological diversity. The primary tenant behind the development of the Convention was that biodiversity is fundamental to human life, and as such, it provides support for ecosystems, for the regulation of water and the atmosphere, and the basis for agricultural production. Recognition was also growing that it is essential that the values of biological diversity be much more fully recognized so that the costs of conserving biological diversity and sustainably using its components is seen as a better alternative in economic as well as environmental terms to allowing biological diversity to be destroyed through unsustainable development practices.

As with any negotiation for a legally binding treaty, there were major policy undercurrents and shifting of positions in the United States by individuals and agencies from the initial stages of the development of the convention and its opening for signature in Rio de Janeiro. But the United States was hardly unique in this regard, many nations made substantial concessions as well as changes in their negotiating positions over the two years of formal negotiations.

But how did the U.S. decide on what its' position would be on specific issues and on the convention as a whole? During the negotiating process, periodic delegation meetings were held prior to the UNEP negotiating sessions. Then Assistant Secretary of State, Curtis "Buff" Bohlen, who headed the negotiations for the United States extended invitations to representatives from all government agencies interested in the negotiations. He also had open meetings with industry and environmental groups during the course of the negotiations. The level of interest and the intensity of the debate continued to increase throughout the negotiating process but really didn't reach a peak until the last two negotiating sessions when the possibility of the negotiations actually producing a treaty became apparent. There were a broad spectrum of agencies represented both by technical and legal experts. Negotiation positions that were at earlier sessions viewed from a technical perspective and the ability of the United States to meet the "intent" of the Convention came to be viewed through a political and legal lens. This caused some problems in the United States' negotiating strategy as in the last round of negotiations we had to make many interventions on the convention floor in order to voice these concerns. Some of these may have been viewed as potentially weakening the conservation principles of the convention but this was not the underlying intent. The U.S. federal system of government that has reserved certain rights to the states has a major impact

¹Paper presented at "A Practical Workshop on Biodiversity Prospecting for Cameroon, Madagascar, and Ghana" held from April 22 to May 3, 1995 at INBio, Santo Domingo de Heredia, Costa Rica.

²The views expressed in this paper are those of the author and do not represent the official position of the U.S. Government or any of its agencies.

on what the U.S. national government can agree to in international agreements. For example, the conservation of most wildlife species, with the exceptions of those covered by specific legislation on endangered species or migratory birds, are managed by our states. Moreover, there were substantial natural resource issues embedded in the Convention that pertained to the activities of all federal and state land management agencies. The United States' ultimate position was to negotiate a convention that would be implementable under current U.S. legislative authorities.

Although progress had been made in the negotiations, there were still considerable disagreement up to the last day of negotiations on access to genetic resources and information sharing and technology cooperation. Moreover, there remained an impasse on issues relating to funding and financial mechanisms, global lists, and intellectual property rights. Also unresolved were the degree of obligation of the contracting parties under the various articles, whether or not reservations would be allowed, and the question of the relationship of this convention to other legally binding international agreements. While the text of the draft convention was considerably improved in an atmosphere of cooperation and mutual accommodation on some issues, there were divisive debates and heated exchanges on others.

Ultimately Mustafa Tolba and Vincente Sanchez ended debate and forced consensus on all issues over the objections by many countries including the United States and France. During the waning hours of the last days, Mustafa Tolba took an increasingly active role in the negotiations and disregarded the views expressed by the United States. This left the United States in an awkward position since many of the most problematic and controversial elements of the convention received little discussion and debate. The United States expressed its' regrets on the haste in which the work was completed and the disjointed approach to the preparation of the convention which left the text seriously flawed from its perspective in a number of important aspects.

The Making of a Decision Not to Sign the Convention

The convening of UNCED in Rio de Janeiro, Brazil in June 1992 represented a milestone along the road to conserving global biodiversity. At that conference however, the United States decided not to sign the negotiated global convention on biological diversity which was completed less than two weeks before UNCED in Nairobi, Kenya. This was in stark contrast to the more than 150 governments who ultimately signed the convention. However, at the adoption of the final text of the convention in Nairobi the United States issued a declaration that detailed its' concerns. Elements that were particularly problematic included the text's treatment of intellectual property rights; finances, including, importantly, the role of the Global Environment Facility (GEF); technology transfer and biotechnology.

The United States' decision not to sign the convention was not made lightly but there were polarized opinions on the appropriate course of action that were heavily debated during that short period of less than two weeks from the end of negotiations to the convening of UNCED. The final decision was heavily influenced by the forceful negative voice of former Vice-President Quayle's Council of Competitiveness and others in the executive branch who felt the convention was too restrictive and unimplementable. They used concerns over access to genetic resources, intellectual property rights, and funding mechanisms to tip the balance away from those for the global environment.

Reconsideration and Attempts at Ratification

The Clinton administration shared the Bush administration's concerns about ambiguities in the Convention's text. Upon taking office, it initiated a review of U.S. options with respect to the Convention. Working with a group of individuals from the pharmaceutical and biotechnology industries as well as representatives from various environmental groups, the administration developed a series of understanding

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relating to the Convention's treatment of intellectual property rights and finances in particular that were generally agreeable to the participants. Most of these groups came to view the ratification of the convention as important to their interests and became strong proponents for its ratification. Many wrote strong letters to the U.S. Senate urging its ratification (Table 1).

Table 1. Partial Listing of Organizations Sending Letters to the U.S. Senate in Support of Ratification of the Biodiversity Convention

<p>American Corn Growers Association American Institute of Biological Sciences Animal Protection Institute American Seed Trade Association, Inc. (ASTA) American Soybean Association Archer Daniels Midland Company Biodiversity Action Network Biotechnology Industry Organization (BIO) Ecological Society of America Institute for Agriculture and Trade Policy International Association of Fish & Wildlife Agencies Merck & Company, Inc. National Cooperative Business Association New York Biotechnology Association, Inc. Pharmaceutical Research and Manufacturers of America (PHRMA)</p>
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Consequently, President Clinton announced his decision to sign the convention as part of the U.S. celebration for "Earth Day" in 1993. It was signed on June 4, 1993 in New York and forwarded to the U.S. Senate for ratification on November 19, 1993. In fact, the Senate Foreign Relations Committee forwarded the ratification to floor of the Senate with a 16 to 3 vote. They recommended that the following understandings be included in the U.S. Instrument of Ratification:

Article 3 - Principle: *The Government of the United States of America understands that Article 3 references a principle to be taken into account in the implementation of the convention.*

Article 16 - Access to and transfer of technology: *It is the understanding of the Government of the United States of America with respect to provisions addressing access to and transfer of technology that: (a) "fair and most favorable terms" in Article 16(2) means terms that are voluntarily agreed to by all parties to the transactions; (b) with respect to technology subject to patents and other intellectual property rights, Parties must ensure that any access to or transfer of technology that occurs recognizes and is consistent with the adequate and effective protection of intellectual property rights, and that Article 16(5) does not alter this obligation.*

Article 19 - Handling of biotechnology and distribution of its benefits: *It is the understanding of the Government of the United States of America with respect to provisions addressing the conduct and location of research based on genetic resources that: (a) Article 15(6) applies only to scientific research conducted by a Party, while Article 19(1) addresses measures taken by Parties regarding scientific research conducted by either public or private entities; (b) Article 19(1) cannot serve as a basis for any Party to unilaterally change the terms of existing agreements involving public or private U.S. entities.*

Article 20 - Financial Resources: *It is the understanding of the Government of the United States of America that, with respect to Article 20(2), the financial resources provided by developed country Parties are to enable developing country parties to meet the agreed full incremental costs to them of implementing measures that fulfill the obligations of the Convention and to benefit from its provisions and that are agreed between a developing country Party and the institutional structure referred to in Article 21.*

Article 21 - Financial Mechanism: *It is the understanding of the Government of the United States of America that, with respect to Article 21(1)(a), the "authority" of the Conference of the Parties with respect to the financial mechanism relates to determining, for the purposes of the Convention, the policy, strategy, program priorities and eligibility criteria relating to the access to and utilization of such resources. The Government of the United States of America understands that the decision to be taken under Article 21(1) concerns "the amount of resources needed" by the financial mechanism, and that nothing in Article 20 or 21 authorizes the Conference of the Parties to take decisions concerning the amount, nature, frequency or size of the contributions of the Parties to the institutional structure.*

It is particularly ironic that after having dealt with all the above concerns, the U.S. has not yet ratified the Convention. Since the negotiations, concerns within the U.S. about the Convention have centered more on its vague nature and its implications for U.S. domestic law and environmental policies. Questions raised by the U.S. Senate include:

- Why does this convention prohibit state parties from making reservations to any of its provisions?
- Will the understandings set forth in the resolution of ratification protect the U.S. interpretation in the event of a dispute?
- Will the U.S. vote in decisions taken under this convention be commensurate with its financial contribution to the funding mechanism?
- Could the eradication of "alien species which threaten ecosystems" called for by Article 8, affect U.S. livestock policies?
- Who will interpret "as far as possible and appropriate," a clause which appears in several places in the convention?
- Will the United States be subject to mandatory dispute settlement?
- How can the Senate, in fulfilling its Constitutional responsibilities to advise and consent, review provisions and processes of the treaty that are not included in the treaty, but will be decided at the Conference of Parties?
- How will the ratification of this convention influence the Endangered Species Act, the National Environmental Policy Act and other domestic environmental legislation?
- Will the provisions regarding access to genetic resources (Article 15) impede United States access to germplasm and other genetic resources contained in international collection centers?
- By what means will the Conference of Parties promote the transfer of technology to developing countries (Article 16)?
- Is it likely or possible that the Conference of Parties may call for a biological safety protocol that will require a license for the transfer of any biologically modified organism?

In response to these questions and those raised by several agricultural organizations, the Department of Agriculture and the Department of the Interior developed the following Memorandum of Record in August 1994 that emphasized the importance of rapid ratification of the Convention:

Benefits to Agriculture

U.S. ratification of the Convention benefits U.S. agriculture by providing leverage to limit the restriction of U.S. exports of biotechnology products, safeguarding U.S. access to agricultural genetic resources, and encouraging conservation of such resources in other countries.

The majority of important U.S. agricultural crops and livestock originated in other parts of the world, and the major sources of the variation essential to future improvements, through traditional breeding and biotechnology, are located outside U.S. boundaries.

Access to this germplasm is essential to continued improvement in the productivity of U.S. crops. For example, experts estimate that our use of plant genetic material to improve agronomic traits and increase yields has added a value of \$3.2 billion to our \$11 billion annual soybean production and about \$7 billion to our \$18 billion annual corn crop. Access to foreign germplasm also helps efforts to facilitate the development of crops resistant to diseases

and plant pests. Bioengineered products are making an ever increasing contribution of major economic value to agricultural advancement.

The U.S. must ratify the Convention by August 30 so that it can participate fully to shape discussions on the regulation of biotechnology that will occur at the first Conference of the Parties in November. There is strong pressure among countries who are already Party to the Convention to push ahead with development of a biosafety protocol on the safe transfer, handling and use of living modified organisms resulting from biotechnology.

Ill-conceived regulation of biotechnology can place undue restrictions on U.S. exports of biotechnology products whether in the agricultural or pharmaceutical areas. One of the many reasons the U.S. biotechnology industry and the Administration believe it essential to promptly ratify the Convention is to ensure that any biosafety protocol, should one be developed under the Convention, is scientifically based and analytically sound, and does not place undue restrictions on U.S. export of biotechnology products.

As the world leader in biotechnology the U.S. must be at the table as a party to the Convention to guide these discussions and protect our interests.

Also likely to be addressed at the first Conference of Parties in November are issues concerning access to genetic resources. The U.S. depends on access to foreign germplasm for plant breeding programs of such key crops as corn, wheat, soybeans, potatoes, cotton, and most vegetables. These crop improvements enhance our ability to provide quality forage for our livestock. In addition, introduction of genetic material from foreign animal breeds into our domestic livestock is crucial for improving livestock productivity, meat and fiber quality and other essential traits.

By becoming a party to the Biodiversity Convention, the U.S. will ensure continued access to genetic resources. Questions of sovereignty over genetic material and concern that holders of such material receive appropriate compensation for providing such material have begun to jeopardize U.S. access to foreign material, particularly in the developing world. Already some U.S. researchers have been excluded from germplasm collections in foreign countries on the basis of such concerns.

The Convention will provide a forum to facilitate access to genetic resources in these and other countries. As a Party to the Convention, the U.S. will be able to work with other countries of the world to develop effective means to safeguard the open exchange of such material, building on the principles of open access and mutual agreement to such exchange. This will ensure and improve our access to important genetic material, whether in private hands, national collections or international centers.

The Convention also encourages conservation of such genetic resources in other countries. All countries, but especially the U.S., will lose if genetic resources of value to agriculture are lost through inadequate or non-existent conservation practices. The U.S. enforces an extensive and effective set of conservation laws, yet this is not the case in most developing countries. The Convention lays out a general framework relating to conservation of natural resources.

The Convention recognizes that if developing countries can benefit from providing their genetic resources to others they will have incentives to make these resources available for use now and in the future. The Convention provides for development of voluntary agreements between the providers of such resources and those who wish to use them.

Private Sector Involvement

As stated in the Report of the Secretary of State transmitted to the Senate by the President, "the participation of the private sector greatly enhances the attainment of economic value from genetic resources." Historically, the private sector in the U.S., including foresters, farmers, and ranchers, has had a vital and critical role in protecting and enhancing biological diversity. In addition, as stated above, agriculture producers need biological diversity to ensure adequate plant and animal genetic resources for improving and protecting domestic production of food and fiber. Access to the world's genetic resources is critical to agricultural production. For these reasons it is imperative that the U.S. agricultural sector participate in future international conferences on implementation of the Convention on Biological Diversity.

We recognize that the private agricultural sector -- by harnessing biological and natural resources -- has produced enormous benefits for the U.S. and its people. The agricultural industry has similar productive contributions to make during consideration of these issues internationally. In this regard, the Administration will conduct briefings and, consistent with applicable law, solicit views on upcoming issues prior to meetings of the

Conference of the Parties and other critical events. The Administration will work to facilitate the participation of representative stakeholder interests, including those from agriculture, as observers at such meetings and, if appropriate and within delegation size constraints, as private sector advisors on the U.S. delegation. In addition the U.S. will use the opportunity of future meetings of the Convention to emphasize the importance of private sector arrangements with regard to the use and conservation of biodiversity.

The Convention may not be used in place of U.S. laws

The provisions of Articles 7 and 8 of the Convention provide a broad framework for the conservation of biological diversity. The United States already has some of the world's most comprehensive and advanced programs for protecting public lands and enforcing environmental laws. In fact, the laws and regulations of the U.S. related to public land management and private land practices impose a higher standard than that called for in the Convention. For example, with regard to protected areas, the President cited, in his Letter of Transmittal, the "extensive system of Federal and State wildlife refuges, marine sanctuaries, wildlife management areas, recreation areas, parks and forests" that already exists in the U.S.

Concerns have been expressed that the implementation of the Convention's conservation provisions may require new environmental laws or regulations or that the Convention itself could be used as the basis for regulatory action. The Administration has determined that neither is the case.

Implementation of the conservation provisions of the Convention will not require any change to any U.S. statute, regulation, or program. As stated in the report to the Secretary of State transmitted to the Senate by the President, "No additional legislation is required to implement the Convention. The United States can implement the Convention through existing Federal Statutes."

The Convention will not provide new authority for any administrative, civil, or criminal action not permitted under domestic law.

The Convention Does Not Prevent Amendment of Environmental Legislation

Concern has been raised that ratification of the Convention by the U.S. could prevent any amendment of U.S. environmental laws. The conservation provisions of the Biodiversity Convention are broad, framework provisions. They are deliberately flexible enough to allow individual countries to determine how the Convention should be implemented, as far as possible and as appropriate for each country. There are many ways that the United States could craft relevant statutes and still remain consistent with the conservation provisions of the Convention. As noted above, in many respects existing environmental laws and regulations impose a much higher standard than what is required by the Convention. Although some basic environmental statutes are necessary to implement the Convention, we do not anticipate a scenario in which the Convention would impede amendment of a domestic environmental statute.

The Convention Does Not Provide for a Private Right of Action

Concerns have been expressed that domestic laws and regulations would be subject to challenge by private persons as not being in compliance with the Convention.

The Convention sets forth rights and obligations among countries. The Convention does not, expressly or by implication, create a private right of action under which a private person or group may challenge domestic laws and regulations as inconsistent with the Convention, or failure to enforce domestic laws or regulations promulgated thereunder.

No Binding Dispute Resolution

Concerns have been raised that the Convention might allow other governments to force changes in U.S. domestic laws and policies through binding dispute resolution. This is not the case. Dispute resolution involving the United States under the Convention is limited to non-binding conciliation. Moreover, such procedures may be initiated only by a Party to the Convention; they are not available to private persons or groups. Binding dispute resolution (either through arbitration or submission of the dispute to the International Court of Justice) is optional. Accordingly, the

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Department of State, in reply to a question from Senator Pell for the record, stated that "the United States will not opt for compulsory dispute resolution under the Convention." This is consistent with past practice in environmental agreements in which the U.S. has not accepted binding dispute resolution.

Effect of Amendments or Protocols on the United States

Concerns have been raised about the possible future impact of protocols to the Convention on U.S. domestic environmental laws. No amendment or protocol is binding on the United States without its express consent. Amendments to the Convention (apart from annexes which are restricted to procedural, scientific, technical, and administrative matters) will be submitted to the Senate for its advice and consent.

With respect to protocols, we would expect that any protocol would be submitted to the Senate for its advice and consent; however, given that a protocol could be adopted on any number of subjects, treatment of any given protocol would depend on its subject matter.

Future Prospects

Currently, the ratification of Convention on Biological Diversity by the U.S. Senate seems unlikely until domestic private property rights and environmental policy issues are resolved. The reauthorization of the Endangered Species Act, the National Environmental Policy Act, the implementation of the President's Forest Plan in the Pacific Northwest, and the reexamination of a host of other policies and laws dealing with the environment are matters of intense debate. The view of the Clinton administration is that the conservation provisions of the Biodiversity Convention are broad, framework provisions. They deliberately leave to individual countries to determine how the Convention should be implemented, as far as possible and as appropriate for each country. Consequently, there are many ways that the United States could craft a statute and still remain in compliance with the conservation provisions. Thus, the Convention should not require any change to any U.S. statute, regulation, or program. No additional implementing legislation would be required. At the same time, the Convention would not foreclose amendment of domestic environmental legislation.

Moreover, the Convention's ratification is further clouded by Senate concerns that the Convention's deferral of a number of important issues to later decisions by the Conference of the Parties constitutes an encroachment on the Senate's prerogatives with respect to its constitutionally mandated advice and consent responsibilities. There is far from agreement on this issue in the Senate, as there are ample precedents for Senate advice and consent to the ratification of framework conventions that, like the Convention on Biological Diversity, defer to the Conference of the Parties important decisions on treaty implementation. Under treaties, the rules of procedure are always decided at the first Conference of the Parties, typically after the Senate has given advice and consent. Examples include the Vienna Convention for the Protection of the Ozone Layer; the Montreal Protocol on Substances that Deplete the Ozone Layer; the UN Framework Convention on Climate Change; the Antarctic Environmental Protocol; the Cartagena Convention (Caribbean); the SPREP Convention (South Pacific); CITES; London (Dumping) Convention; Convention for a North Pacific Marine Science Organization (PICES); Convention for the Conservation of Anadromous Stocks in the North Pacific Ocean; and the Convention for the Conservation of Salmon in the North Atlantic Ocean.

The above concerns, no matter how unfounded, continue to be a major roadblock for the Convention's ratification. Hopefully in the near future, as current U.S. domestic environmental policies and laws are reviewed and reauthorized, the road towards ratification will be cleared.

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