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**Access to Genetic Resources:
An Evaluation of the Development and
Implementation of Recent Regulation and
Access Agreements**

PREPARED FOR THE BIODIVERSITY ACTION NETWORK

BY

**ENVIRONMENTAL POLICY STUDIES WORKSHOP, 1999
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FOREWORD

Every year, the School of International and Public Affairs of Columbia University in New York organizes an environmental policy studies workshop. In 1999, a team of graduate and post-graduate students with broad ranging expertise prepared this timely and policy-relevant comparative study of legal agreements regulating the access to genetic resources for the Biodiversity Action Network, a non-governmental organization based in Washington, DC. The team was directed by Pamela Chasek, Ph.D. of Columbia University.

The Biodiversity Action Network, commonly known as BIONET, is a network of over 50 US environmental organizations concerned with biodiversity conservation, sustainable use and equitable sharing of benefits from such use. In other words, we promote and monitor the implementation of the Convention on Biological Diversity (CBD), and have had an interest in the access to genetic resources issue for several years. Within the field, environment and development organizations repeatedly voice concerns about lack of progress in establishing equitable benefit sharing arrangements at the community level; national governments and indigenous peoples representatives level accusations of bio-piracy; taxonomic researchers complain about cumbersome procedures regulating their field work; and companies argue that increased transaction costs in bio-prospecting may lead them to explore other avenues. Such concerns are a far cry from the promise of "green gold" several years ago.

Context and Scope

The Convention on Biological Diversity is considered by many to be a progressive instrument when it comes to establishing legal instruments to protect and regulate biodiversity at the national level. While CBD discussions around issues such as forests and biosafety have been beset by numerous political obstacles, the momentum to develop legislation regulating access to genetic resources at the national level has continued to strengthen. With an assortment of models now in effect, many of which are highlighted in this report, other countries are watching and drawing lessons from those experiences for application in their own national context. Furthermore, many from both the governmental and non-governmental communities see access legislation as playing a key role in other important CBD issues, such as benefit sharing, traditional knowledge and intellectual property rights.

In this regard, the CBD contains important provisions recognizing the rights of indigenous and local communities and the important role they play in the conservation of biodiversity, especially in regard to access to genetic resources and benefit sharing. At the fourth Conference of the Parties to the Convention (CoP-4), May 1998, the linkages between the two issues were further recognized and an expert panel established. The panel will convene in October 1999 in Montreal in order to provide input into discussions at CoP-5, to be held in Nairobi in May 2000, where access to genetic resources will be a key theme. Additionally, an inter-sessional meeting of the CBD in June 1999, will provide input to CoP-5 on access to genetic resources and benefit sharing.

This study provides a valuable complement to existing and ongoing work in the field. Its comparative focus on a number of specific cases while addressing both structure and implementation contributes to other work focussing either on the mechanics of legal frameworks or single, case specific studies. Such analytical work will become increasingly valuable as more countries start developing their own legislative and regulatory instruments, and stakeholders such as the private sector, botanical gardens and seed banks consider their role in access agreements.

It should be noted that the authors decided to focus this report on genetic resources generally used for pharmaceutical purposes, and not on agricultural resources. Given the expertise available to them and the specifics of the subject matter, a focus on both would have unduly complicated the study. They also recognized other materials and ongoing work relevant to the agricultural resources topic (e.g., from the World Resources Institute, IUCN - The World Conservation Union, the Food and Agricultural Organization of the United Nations [FAO] and the Consultative Group on International Agricultural Research [CGIAR]). Despite this limitation in scope, we are quite pleased with the wealth of information uncovered and the stimulating analysis. Moreover, in light of the above mentioned timetables the report is quite timely, and we are convinced it will attract a wide readership of policy-makers, practitioners and advocacy organizations.

Property Rights

One of the main problems in regulating access to genetic resources lies in the tension between property and use rights over land, which may be private or community-based, versus the sovereign rights of countries over the genetic resources that the land contains. To make matters more complex, intellectual property rights (IPRs) over genetic information, which remain intangible until applied, are part of a difficult debate over patent regimes. When regulating access to genetic resources it is important to recognize and account for these linkages, and the study excels in highlighting.

Part of the reason why the IPR debate is different between the pharmaceutical and agricultural industries is the high-value, low volume character of pharmaceutical bio-prospecting. On the other hand the use of agricultural resources is complicated by a vast array of seed banks and ex-situ collections, which fall outside the CBD's purview and the sovereign right of countries of origin (the CBD does not apply to such collections in existence prior to its coming into force). In this regard, negotiations are currently ongoing under the auspices of the FAO to address these issues through harmonization of the International Undertaking on Plant Genetic Resources with the provisions of the CBD.

However, in parallel to such discussions on access and genetic resources, important developments under the World Trade Organization (WTO) may well overtake CBD deliberations. As part of the trade liberalization agenda, a regime for so called Trade-Related Intellectual Property Rights (TRIPS) has been established to harmonize standards regulating the use and protection of knowledge. The TRIPS regime is complex and fraught with conflicts between developed and developing countries. Its 1999 review of the provisions in Article 27(3)b covering plants, animals, and essential biological processes and a full review in 2000, will have a major impact on the shape of future legal regimes regulating the access to genetic resources. Additionally, the CBD's recognition of sovereign rights over genetic resources can be interpreted to conflict with WTO principles regarding non-discrimination and most-favored nation status.

Further effort is also necessary to protect and encourage development of the traditional knowledge of indigenous peoples and local communities, which is currently poorly accommodated within the TRIPS regime. Numerous examples of the misappropriation of such knowledge exist, including efforts to patent uses of the neem tree from India and recent efforts within the US to challenge a patent on the use of Ayahuasca, a plant commonly used for medicinal and religious purposes in the Amazon. In view of work on TRIPS in 1999 and 2000, the CBD may well be too late to provide substantial input when devising its decisions on the matter at CoP-5.

Benefit Sharing

The prospects to reap a share in bio-prospecting profits were clearly one reason for developing country enthusiasm for the CBD. However, to date these profits have been elusive, and the win-win opportunities foreseen when uniting environmental and development objectives have been few and far between. The authors of this study have found this true in the cases studied here. They rightly conclude that technology transfer and capacity building is preferable over arrangements anticipating financial windfalls, which may never materialize. This does raise the issue of how to equitably distribute non-monetary benefits from access agreements to various parties, in particular local communities. Another element highlighted by the study is how contractual agreements can facilitate access and avoid potential problems around IPR. However, as long as uncertainty remains about the TRIPS review and, in particular, the US position on patenting, some of these agreements may need re-negotiation in the near future. Strong arm tactics, including the imposition of trade sanctions, currently employed to impose the US position on countries with different IPR regimes are, in our opinion, an unfortunate way to make the argument.

Additionally, one must recognize the volatility and uncertainty within the market, even within the US. Recently, Shaman Pharmaceuticals, a company dedicated to benefit-sharing through its work with the Healing Forest Conservancy, was forced to restructure as the costs of further clinical trials for an anti-diarrhea drug to be marketed in the US proved prohibitive. Shaman will now focus on the botanicals market, thereby no longer seeking FDA approval for pharmaceutical products.

For this and other reasons, the lessons to be learned from this study for the future of benefit-sharing arrangements will prove valuable.

Stakeholders

As is clearly shown in this study the process by which agreements granting access are developed is important to their viability, as well as the acceptance of outcomes by all relevant stakeholders. But, who are those stakeholders? And, what interests do they represent?

The research community spans a continuum from pure to applied research. Agreements need to reflect the changing reality of the increasing commercial value of academic research. In the US, the overlap between university research centers and the private sector has already led to problems in establishing what knowledge should be in the public domain as opposed to becoming proprietary. It is important in this regard to carefully define the various contracting parties; is it the individual researcher, the academic institution or the research center?

When speaking of the private sector, we often forget that it is not monolithic. While in the bio-prospecting business many private sector entities are multinational corporations, some are small community-based industries, with a different set of needs and perspectives. From a development standpoint, it is important to ensure that access activities enhance local value-added activities and not just promote further resource flows from South to North.

Governments are also not the singular entities they are sometimes considered to be. As this study shows, in the cases of the US and Brazil, with federal systems, governments negotiate as much within themselves as with outside stakeholders. In other cases, local or regional administrations are as much a stakeholder deserving a seat at the table as technical agencies.

Local communities, in particular indigenous peoples, are playing on a field that is leveled against them. As resource managers, they are responsible for the sustainable maintenance of a resource base, but in most cases they lack the resources to pursue IPR and patenting claims.

While they may find short-term employment or obtain training as part of a project, such groups rarely have the resources to negotiate equally with governments and the private sector alike. Governments often do not give due recognition to communities, providing a disincentive for continued sustainable use. Therefore, the recognition and presence of indigenous peoples and local communities, in particular of women, in the process of establishing agreements governing access is crucial if we aim to promote biodiversity conservation.

This brings us to the question of how to balance the need to limit the number of parties at the negotiating table with the need to have a negotiated agreement acceptable to all relevant stakeholders. While recognizing the need for direct stakeholders to participate in negotiations, many hesitate to make allowances for the interests of indirect stakeholders. However, as the US case study shows, the process does need to recognize the larger political context. Failure to do so may delay implementation indefinitely or substantially increase costs. No one formula exists for resolving this dilemma, as the study shows that much depends on the specifics of the case and the national context. One thing is becoming clear, interlocking agreements between e.g., local communities, regional government and research groups and between research centers, the government and international partners, containing clauses to address contingencies regarding IPRs, commercial applications, etc., may prove to be the best available model. It would therefore be useful for countries to report to the CBD Secretariat on models and examples regarding best practices of inter-locking agreements.

Finally, as pointed out in the study, monitoring and evaluation of agreements is in most cases weak or absent altogether. The apparent lack of capacity in agencies tasked with enforcement and compliance clearly requires additional attention, as well as ensuring that access agreements or legislation do promote CBD objectives. We, however, also need to recognize that it is difficult to enforce provisions in the field. This may lead us to reconsider alternative enforcement mechanisms, for example by independent international agencies or government agencies in the country home to the entity requesting access or where the genetic material is destined for processing. Regardless of the solution, agreements need to be structured to address this concern from the start.

For Bionet this has been a valuable exercise, as the team from Columbia University has provided us with a timely, policy-relevant comparison of the first generation of legal arrangements regulating access to genetic resources. It is an important addition to the literature in the run-up to the upcoming series of international meetings deliberating on the topic. We would like to thank them for the excellent work done over a period of only three months. While the comprehensive nature of the study may deter some from delving too far into the report, an executive summary has been prepared containing highlights and recommendations. However, we do encourage you to browse and take a closer look at the methodology and case studies.

We look forward to hearing from you on how the study has informed your work. At BIONET, we will continue to monitor the international policy debate on this issue and welcome comments and other contributions to inform our own work.

Washington, DC, May 1999

Hans J.H. Verolme, coordinator, and Stas Burgiel, program officer

For more information about the Biodiversity Action Network visit www.bionet-us.org or subscribe to the biodiversity policy listserver "biodiv-conv" at majordomo@igc.org (subscribe biodiv-conv <youremail>).

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EXECUTIVE SUMMARY

In signing the 1992 Convention on Biological Diversity (CBD), the governments of the world committed themselves to creating policy and legislation to simultaneously regulate and facilitate access to genetic resources (AGR) in the interest of three interrelated goals: biodiversity conservation, sustainable economic development, and socioeconomic equity. Progress in this codification of genetic access policy varies substantially from nation to nation, as a diverse field of "stakeholders"—including resource owners, cultural groups and communities, corporations and industrial coalitions, government hierarchies, environmental advocates, and scientists—struggles to reach a point of converging interests.

To achieve the goals of the CBD with regard to genetic resources, policy makers must overcome four primary obstacles. First, they must factor the special character of genetic resources into access policy. Genetic resources are both tangible (physical) and intangible (information), and they are distributed independently of political boundaries. Second, genetic resources have been used, modified, and stored in centers around the world for centuries, and effective policy must accommodate these *ex situ* collections. Third, before addressing the complexities of the distribution of benefits, policy makers must clearly define ownership and tenure of genetic resources. This is a difficult task, because groups as varied as humankind, states, regions, and locals have all claimed rights over genetic resources; the matter is further complicated by the conflict between customary and legal property rights. Fourth, the dearth of legal, institutional, and scientific capacity in many countries seriously hampers efforts to facilitate and regulate access to genetic resources. Finally, the often conflicting interests of large numbers of stakeholders must be reconciled if policy is to be successful.

In this report, we examine and critically evaluate the efficacy of seven examples of AGR agreements in overcoming these obstacles and achieving the three goals of the CBD. These cases were chosen because they represent a broad array of policy responses involving a variety of stakeholders, including private actors, non-governmental organizations (NGOs), research institutions, and state representatives; because they represent different geographic regions; and because adequate data were available for analysis. Specifically, we examined

- The National Biodiversity Institute (INBio)–Merck & Co., Inc. Research Agreement in Costa Rica
- The National Cancer Institute–Universidade Paulista agreement and proposed legislation in Brazil
- The BioAndes attempt to bioprospect in Colombia under Decision 391 of the Andean Pact
- The African International Cooperative Biodiversity Groups' research and development agreements in Cameroon
- Access agreements and legislation in the Philippines
- The Strathclyde Institute of Drug Research–University of the South Pacific agreement in Fiji
- The Yellowstone National Park–Diversa Corporation agreement in the United States.

Of each case we asked the following questions, which form the basis of our analysis:

- How are stakeholders identified and represented?
- How are property rights addressed?
- How is prior informed consent ensured?

- How are benefits distributed?
- Do the terms of the agreement encourage compliance and are there mechanisms in place to handle disputes?
- How are sustainable use and conservation addressed?

A number of conclusions emerged from our analysis, and these led to several recommendations that are pertinent to policy and decision makers involved in regulating AGR.

During policy development existing regional institutions and cooperation frameworks have provided operational support. One way to make regulatory efforts more expeditious and cost-effective is by using a regional cooperation framework to coordinate legislation development. Similarly, an academic or NGO cooperation framework may assist in coordinating bioprospecting efforts. It can also serve to avoid duplication of efforts and allow for the coordination of regulatory regimes among neighbors. But working in a regional framework has its disadvantages. The realities of implementing a regional regulatory regime shift point to a more complicated scenario. There may be inconsistency in the implementation, and regional legislation may be more difficult to change in the future.

Recommendation: We recommend that nations which currently do not have the capacity to develop regulatory regimes take advantage of existing regional institutions that can aid them in the process.

New AGR regimes lack evaluation procedures which would allow an assessment of achievement of the CBD objectives. Although it is still too early to evaluate the conservation and sustainability of the access to genetic resources regimes that are currently operating in the agreements we examined, it will be essential to assess their effects. Agreements often require assessment of compliance with their own terms, but they lack specific provisions that mandate post-agreement assessment of their impacts on sustainable use, conservation, and equitable distribution of benefits in the long term.

Recommendation: Independent, multidisciplinary evaluation of the success of the access policy in achieving CBD objectives must be incorporated into AGR regimes. It would be pertinent to consider this issue during negotiation of agreements so that training of in-country persons in this area or the hiring of consultants to perform this task can be arranged. In those agreements that must be periodically renewed, the renewal process could require an evaluation report.

Minimizing the number of parties facilitates the establishment of agreements, but may ultimately lead to failure by excluding the interests of relevant stakeholders. Most of the cases involve access to publicly owned lands, thereby eliminating the need to consult with private parties or indigenous groups prior to gaining access to genetic resources. Participation of all stakeholders is essential to effectively implement regulations and achieve the long term goals of the CBD; failure to recognize and involve stakeholders during the formulation of agreements may jeopardize their successful implementation.

Recommendation: During the policy development process the entities directly involved in policy formulation should attempt to identify and seek the participation of other stakeholders.

The ability of regulated AGR to expand conservation efforts is limited because most agreements take place on land where conservation is already underway. In an effort to facilitate the establishment of agreements and maximize diversity of resources they have access to, bioprospectors seek areas where (1) property rights are clearly established, (2) a minimal number of parties are involved in negotiations, and (3) biodiversity is high. Frequently, this leads them to target state-owned national parks and other protected areas. However, this strategy fails to augment current conservation efforts and therefore limits the impact access regulations can have in transforming land-use practices.

Recommendation: Bioprospecting initiatives based outside protected areas should be encouraged.

There is a contradiction between disclosure of terms in access agreements for stakeholder involvement and right to confidentiality of parties in the transaction. Whereas it is common business practice for the terms of agreements to remain confidential, arguably the public has the right to know the details of a financial arrangement which concerns the transfer of genetic information obtained through prospecting on public land. Although it may not be feasible to address this issue in the short term, we believe it is important to highlight the difficulties associated with the current state of affairs so as to stimulate the discussion of this topic. The fact that a large portion of current worldwide bioprospecting is done on public lands adds relevance to this issue.

There may be few incentives arising from access to genetic resources to preserve resources that local communities do not legally own. Governments have asserted their sovereign rights over genetic resources, but in many cases the land remains under traditional tenure while the property rights system grants ownership of all genetic resources therein to the state. Usually, only resource owners and users participate in the negotiation of agreements, and only the resource owner receives the benefits. The burden of sustainable use and conservation, however, rests on the communities. It is unlikely that sustainable land-use practices will be embraced by local communities if AGR policy does not provide them with ownership of the genetic resources they tend and benefits derived therefrom.

Recommendation: National policy should address the conflict between traditional land tenure and legal property rights of genetic resources, so as to match conservation obligations with the benefit sharing rights implicit in AGR policy.

AGR regulations may raise the costs of negotiating access and create a disincentive to use biodiversity. Pursuant to the goals of the CBD, AGR policy aims to both regulate and facilitate access. Clearly defined regulatory protocols can facilitate access by informing potential users of source-country requirements prior to initiating the application process, but only if the regulations are not prohibitively restrictive. Extreme regulation raises the overall cost (monetary and otherwise) of using genetic resources—many of which were easily accessible until recently—and may prevent genetic resources from being used. This problem affects national, international, commercial, and non-commercial ventures alike. Because the goals of conservation and distribution of benefits can only be achieved if genetic resources are accessed, it is imperative that policy makers reconcile the potentially conflicting goals of regulating and facilitating access

to genetic resources.

New AGR regulations may further increase the cost of negotiating access by nullifying pre-existing agreements or requiring renegotiation of terms. Consequently, the often lengthy process of developing regulations creates a "window of uncertainty" during which parties are reluctant to apply for access, and source country authorities are inclined to reject or postpone them.

Based on the cases we examined, it is difficult to determine the extent to which the balance between regulating and facilitating access has been achieved. The complexity of the issue is illustrated by the failed BioAndes applications to gain access in Colombia. In the Philippines only two of 37 applications have been approved, but it must be noted that these two successful cases will most likely serve as templates for future applications, thereby improving the chance of their approval.

An additional hindrance to AGR is the use of the same standards in commercial and non-commercial research access requests. Since commercial access deals with such high monetary stakes, access regulations have become increasingly restrictive and commercially-oriented. Hence, a cumbersome, unnecessarily strict application process is imposed on what is considered basic, not-for-profit research. This basic scientific investigation is required to understand natural processes and almost invariably precedes commercially oriented research. Failure to explicitly recognize the fundamental differences between commercial and non-commercial research in AGR policy may cause essential research to grind to a halt. For instance, full enforcement of Decision 391 in Colombia would render all current scientific collection projects inside the country—including those performed by national universities and state agencies—illegal. However, it is often impossible for source country authorities to distinguish between commercial and non-commercial projects.

Recommendation: Since there is no objective criterion to draw the boundaries between non-commercial and commercial research, and to avoid discouraging research that may benefit biodiversity conservation, we recommend that countries provide a "two-track" application process, wherein any access applicant would be able to choose between either one of the two "tracks" according to their priorities.

- Type I agreement: A simple research permit in which researchers forgo the right to any future monetary benefits arising from commercialization and IPRs, which belong to the resource owners.
- Type II agreement: A more complex contractual agreement which would involve negotiations of IPRs and both monetary and non-monetary benefits with the resource owners, as defined in the specific national and local context.

The advantage of this system is that the users themselves define their intentions, avoiding the need to infer them from the project description or other criteria. Large numbers of stakeholders must be consulted and detailed terms of benefit sharing negotiated only when IPR and financial benefits are an issue. By stating in a legally binding agreement that they do not claim any ownership rights over future commercial discoveries and resulting benefits, parties interested only in basic research could avoid more costly negotiations. Somewhat counter-intuitively, the

Type I agreement represents one of the most restrictive agreements possible, in which users are only granted ownership to the sample itself and permission to study the material they collect.

It must be noted that the Type I agreement would not preclude the need for fair compensation—either monetary or in-kind—to the local community, source country, or source-country institutions, as provided by their regulations. It would also not preclude the commercialization of the discoveries by the resource owners. Furthermore, it would not prevent users from entering into a more complex Type II agreement equipped with benefit sharing provisions in the future.

Type II agreements could be structured as a framework agreement containing a variable number of clauses that come into effect as they become applicable. Although the uses permitted in the Type I agreement could be viewed as the first step in the establishment of the Type II agreement, treating them as completely separate agreements underscores the fundamental differences between commercial and non-commercial ventures and encourages the basic biological research that is essential to achieving the goals of the CBD by preventing over-regulation.

The main benefits to be obtained from access agreements will most likely be non-monetary, i.e., capacity building, technology transfer, joint research, and training. A common argument in AGR discussion, as it relates to the goals of the CBD, is that substantial cash profits that would enhance conservation can be generated from bioprospecting. Nonetheless, at the time of this analysis, no royalty or commercialization-derived monetary benefits have resulted from any of the agreements. During this study, we noted a heightened awareness of the costs and risks associated with bioprospecting.

Many of the access agreements we reviewed strongly emphasize the training and capacity-building responsibilities of the foreign parties. Thus, source countries collect the significant non-monetary benefits that prospectors are willing to exchange for access from the very beginning of a project. Therefore training and capacity building, as emphasized by these agreements, are likely to be much more important than monetary benefits in the short and long term. They may also address conservation goals in a shorter term.

Recommendation: When establishing agreements all parties should acknowledge that benefits obtained from access will for the most part be non-monetary and that monetary benefits may be elusive.

In conclusion, do the agreements we examined provide ways to overcome the obstacles to regulating access and achieving the goals of the CBD? As can be expected, the degree to which they accomplished this varies among the cases examined and the types of obstacles. Some of the obstacles outlined here seem to be very difficult to overcome, while others are being reduced.

Those obstacles arising out of the nature of genetic resources—such as the difficulties in dealing with genetic resources as information—are more difficult to overcome, but can be incorporated when designing and evaluating regulations or agreements. The incongruence between the political framework and the geographical pattern of ecosystem distribution may be addressed more effectively in those cases where regional initiatives are under way.

The conflicts surrounding property rights have not been addressed successfully, essential as this is to the implementation of benefit sharing mechanisms. As was discussed above, the complications that arise out of the new, post-CBD genetic resource ownership regime are still relatively unexplored, and they must be overlaid on centuries-old land rights strife.

As illustrated by the Yellowstone–Diversa agreement and the differences between the alternative federal bills in Brazil, reconciling the diverging interests of stakeholders remains a challenge in many instances. But in others, such as the agreements in Fiji, the involvement of a variety of stakeholders seems to have resulted in a satisfactory arrangement for all involved.

In the case of *ex situ* collections, the practicality and rationale of repatriating museum collections and herbaria are severely questioned by the scientific community. Scientists argue that the disintegration of large collections would hinder research activities and that most developing nations would find the cost of maintaining large scientific collections to be prohibitively high.

The obstacles arising out of low institutional, legal, and scientific capacity are most rapidly affected by AGR agreements and regulations. Examples abound in our case studies of instances wherein the development of a private contract greatly improved the ability of a country to handle requests for access. As those countries currently developing legislation implement it, and if they recognize the consequences brought about by over-regulation, it is expected that access procedures will become clearer and more effective for both national and foreign interests.

We hope that the recommendations we provide here will be considered by policy makers, for we feel that they highlight areas that need to be addressed if countries are to achieve the objectives of the CBD.

INTRODUCTION

In signing the 1992 Convention on Biological Diversity (CBD), the governments of the world committed themselves to enacting policy and legislation to simultaneously regulate and facilitate access to genetic resources (AGR) in order to achieve three interrelated goals: 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. Progress in genetic access policy varies substantially from nation to nation, as diverse stakeholders—including resource owners, cultural groups and communities, corporations and industrial coalitions, state agencies, environmental advocates, and scientists—struggle to reach consensus.

To date, few countries—notably the Philippines, Costa Rica, and Andean Pact signatories—have enacted regulations in response to the CBD mandate concerning access to genetic resources. Many other states have formulated draft legislation that is now in the lengthy process of ratification, subject to intense review and lobbying by stakeholders whose interests have yet to be reconciled. A May 1998 workshop in Bratislava, Slovakia, noted that the perspective of users of genetic resources differs greatly from that of providers. Whereas the former are interested in creating quick and simple procedures to obtain the prior informed consent of providers to bioprospect, the latter want to be sure that the AGR regime created ensures that their interests are well represented.¹ The ongoing debate concerning these varying interests has served to slow the development of access regimes around the world.

Despite the slow movement of national legislation, access to genetic resources has begun to change in practice. Notably, in an attempt to catalyze the implementation phase of the CBD, environmental non-governmental organizations (NGOs), such as the International Cooperative Biodiversity Groups (ICBG) and the Biodiversity Conservation Network, have brought stakeholders together in agreements to trade in genetic resources. Similarly, some private companies have agreed to and sought to comply with stricter standards of access to raw genetic materials.

This change in practice prior to new legislation supports the view that globalization is gradually allowing international policy and industry to bypass the authority of the state. It may also be a fortuitous opportunity to pre-test and evaluate specific policies prior to codification—in effect, allowing new or modified custom to influence, if not fully determine, law. Conversely, the effect of allowing practice based on a loose framework convention such as the CBD to determine law may result in incoherence and conflict rather than a healthy diversity of responses tailored to the individual interests of each nation, interest group, and ecosystem. The effect of such incoherence could stall or, in the extreme, subvert beneficial legislation, thereby rendering the CBD less effective in achieving its environmental and humanitarian goals. Therefore, in order to ensure the success of the CBD, it is important to closely monitor developments in the genetic access and benefit-sharing regime.

In this report, we examine and critically evaluate the efficacy of seven examples of AGR agreements in achieving the goals of the CBD. We begin in Chapter I by reviewing the historical and theoretical context of the issue, and elucidate the obstacles policy makers must overcome in order to achieve the goals of the CBD in Chapter II. Each AGR agreement was treated as a case

study, and the empirical data derived from each case are reported in Chapter III. In an attempt to discover the strengths, weaknesses, and general trends inherent in the cases, we provide a crosscutting analysis in Chapter IV, followed by our conclusions and recommendations to policymakers, advocates, and practitioners in Chapter V.

CHAPTER I. BRIEF HISTORICAL OVERVIEW: THE EVOLUTION OF GENETIC RESOURCE VALUE AND REGULATION

Although the conceptual perception of genetic materials as resources of quantifiable economic value is a rather recent phenomenon, the knowledge and mastery of biological surroundings has been critical to the survival of every human culture.² The wealth of genetic resources in the form of crop germplasm has for centuries enriched those states with the power and resources to seek and acquire it from remote colonies. By the time of Smith and Ricardo, colonial states had already introduced exploitation of genetic resources to areas of the world whose natural and agricultural biota exceeded by far that of the colonial powers. In a sense, Christopher Columbus was no more than a bioprospector bound for East Asian "Islands of Spices" when he accidentally bumped into an undetermined Caribbean island and introduced the Western agricultural world to potatoes, maize, tomatoes, peppers, tobacco, peanuts, cassava, and countless fruits and herbs.³

The value of genetic resources has greatly increased in the last 500 years. Plant and animal breeding in the 18th and 19th centuries produced highly specialized varieties that were of high value in the market economy of the time. The emerging breeding industries in England sought economic protection over these artificially selected varieties, which led to the establishment of intellectual property regulations.⁴ For the first time, property rights were extended beyond ownership of the physical entity to a specific breed of that species. This breed or variety we now know to be a specific combination of genes that results in a unique and recognizable morphology. Over the course of the last century, the science of genetics has further increased our ability to manipulate and categorize these varieties. As a result, property rights have been refined to include protection over specific genes or proteins that contribute to the value of the variety. In the last 20 years, advances in biotechnology (such as recombinant DNA technology) have made it possible to take a gene from one organism and integrate it into another, distantly related organism. This new technology has greatly increased the potential uses and, hence, the value of genetic resources.

Biotechnology is limited, however, in that it still depends on naturally occurring biodiversity to supply the raw material for advances. Access to biodiversity has traditionally been largely open; in the case of crop genetic resources, access to germplasm was considered "a right going back 12,000 years to the dawn of agriculture."⁵ This perspective has resulted in a great inequity whereby common-pool genetic resources are freely obtained for use as raw materials in the production of secondary products that are subject to proprietary protection and profit. This has become a concern for developing countries, where the bulk of the world's biodiversity is located, whereas the technology to manipulate genetic material belongs to the global corporations and research institutions of developed countries own. Therefore, most profit from genetic resources obtained in developing countries is gained by companies and institutions in developed countries. Although numerous examples of attempts to restrict transfer of germplasm do exist,⁶ general policies on enforcement have been slow to emerge.⁷

In 1989, the United Nations Food and Agriculture Organization (FAO) International Undertaking on Plant Genetic Resources, which originally defined plant genetic resources as the "heritage of

mankind . . . [which] should be available without restriction,"⁸ attempted to resolve this inequity by establishing farmers' rights restricting the transfer of germplasm developed through artificial selection.⁹ From the perspective of the biodiversity-rich developing world, however, the FAO Undertaking did not create an equitable AGR regime to overcome the growing trend towards intellectual property "monopolies" on genetic information.¹⁰ These monopolies were created by the 1991 Uruguay Round of the General Agreement on Tariffs and Trade (GATT). At this conference, the scope of intellectual property rights (IPRs), until then a matter of national jurisdiction, was expanded by its association with global trade. The resultant mechanism—trade-related intellectual property rights, or TRIPs—allows the discovery of and applications arising from genetic information to be treated as any other form of intellectual property,¹¹ effectively creating a method of privatization at the international level. Although they conflict with the moral and ethical values of some nations¹² and most prior customary practice regarding the transfer of genetic material and knowledge, TRIPs on genetic resource-related information are a powerful mechanism of establishing ownership over genetic resources.

The urgency to address the issues surrounding access to genetic resources has increased in the last 20 years. Advances in biotechnology have increased the potential value of genetic resources while the rate of loss of biodiversity due to human activities has also continued to increase. Developing nations have seen the emerging AGR regime as an important opportunity to improve their position in global politics and obtain much needed capital for development. They viewed the CBD—which was the result of increasing global concern over the rapid extinction of species—as a means to control the transfer of their genetic resources and information, which led them to reject an initial draft in which biodiversity was considered the common heritage of humankind.¹³ The long and convoluted history of genetic resources encumbers any attempts to establish a functional AGR regime.

CHAPTER II. OBSTACLES TO REGULATING ACCESS TO GENETIC RESOURCES AND ACHIEVING EQUITABLE DISTRIBUTION OF BENEFITS

Past and present uses of biological resources and biodiversity conservation theory have led policymakers to perceive genetic resources as economically valuable assets whose access must be regulated to ensure sustainable use. If we are to evaluate the success of existing efforts to regulate access and the goals of the CBD, we must first explore the obstacles policymakers must overcome.

There are five major obstacles to regulating access to genetic resources and achieving equitable sharing of benefits, including (1) the special character of genetic resources; (2) the existence of vast *ex situ* collections; (3) difficulties in establishing ownership of these resources; (4) the dearth of legal, institutional, and scientific capacity; and (5) the conflicts of interests among different stakeholders.

SPECIAL CHARACTER OF GENETIC RESOURCES

The nature of genetic resources

The very nature of genetic resources complicates valuation, a necessary step in establishing the genetic resource market that the CBD aims to utilize. According to the CBD, genetic resources are any material of plant, animal, microbial, or other origin that contains functional units of heredity of actual or potential value. The material and geographic aspects of genetic resources pose an extraordinary challenge to national and international policymakers because most living organisms reproduce and disperse naturally, irrespective of the restrictive measures that policymakers wish to lay on them. This biological fact is compounded by the elusive nature of information as value added: information, even when derived from biological material, is intangible and therefore requires a special property regime.

The overall value of biological diversity—and the genetic resources it constitutes—rests on the total impact of the marginal conversion of land-use to specialized biological resources. The resulting value can be divided into static (material, tangible) and dynamic (information-based, intangible) components. The static value of genetic resources is the sum of its *conversion value* (often considered negative at any given time, since it is instantly more profitable to convert land to, for instance, intensive monocropping) and the *value of retention* of a wider range of assets within the biological system.¹⁴ These "assets" or "services" include, but are not limited to, the role of biodiversity as a carbon sink, pest control, and its aesthetic and recreational importance.¹⁵

The dynamic value of genetic resources derives from its *option value*—the value of certain characteristics known in plant and animal varieties which may prove useful in facing new environmental and health challenges—and the *exploration value* inherent in the possibility of finding a useful natural compound. The latter is the value with which parties are concerned when negotiating agreements on benefit sharing derived from bioprospecting, and it seems to be the one that most urgently concerns measures to restrict access.

Biotechnology has added considerable value to genetic resources. The "biotech" century has seen profits from some genes and/or organisms that today rank in the order of millions of dollars, e.g., *Thermus aquaticus*.¹⁶ Biotechnology has allowed for companies and individuals to characterize organisms and genes as precisely as one would describe an invention, blurring the once clear distinction between products of nature and products of human ingenuity. Since biological entities can now be described and utilized with the precision of manufactured objects, lawmakers are increasingly allowing patents for genetically engineered products.

Despite the spirit of patent laws requiring innovation, non-obviousness, and usefulness, genetic resources today may be considered closer to human "inventions" than to natural "discoveries" in legal terms.¹⁷ Thus, bioprospectors are able to reap profits from living organisms (or products derived therefrom) that would have been considered "common goods" only a century ago. The legislative response is, of course, attuned to the higher stakes in the current genetic resources market, but it might, overlook the fact that these resources did not originate entirely in the laboratory.

As a result of conversion pressures, the cost of maintaining genetic resources has abruptly risen, whereas advances in biotechnology have caused the potential returns from genetic product development to skyrocket. Consequently, governments have demanded agreements on benefit sharing in order to receive part of the profits—financial or otherwise—that the dynamic value of biodiversity entails.¹⁸ Nonetheless, the difficulties in characterizing and assessing the value of genetic resources are pervasive.

Political boundaries vs. natural biological ranges

As inadequate as the global inventory of biodiversity was in the mid-19th century, even then biologists realized that most plants and animals have restricted geographical ranges. Nonetheless, species distribution has very little to do with capricious political boundaries. As the world was progressively charted, the concentration of large numbers of life forms in areas close to the equatorial line became an established biological fact. Once the loss of biological diversity became a global concern, nation states became the key actors in the process of international collaboration that culminated in the signing of the CBD in 1992.

This state-oriented approach, inevitable in the context of international policy, is not necessarily the most appropriate for the conservation of genetic resources that are distributed in patterns that reflect evolutionary, not political history. The world is not a zoo with borders separating parrots from ibises. This is why many countries may rightfully—but fruitlessly—claim ownership of the species and/or genes that range freely across their borders. Academics, bioprospectors, and local communities alike have criticized the absolute sovereignty of nation states over resources that have been preserved (and often improved) by culturally distinct communities.¹⁹ These political factors, which are the product of history, geography, and strategic interests, make regulating access a very complicated matter.

EX SITU COLLECTIONS

Museum collections

The number of species of living organisms on Earth is currently a subject of debate, where educated guesses range from several to one hundred million.²⁰ Of these, approximately two million species are known to science and are deposited in herbaria, arboreta, and museum collections. Access to genetic resources stored in these collections is generally open, operating at the level of academic cooperation. The major taxonomic collections are located in developed countries where biological sciences have been traditionally endorsed by governments and wealthy patrons. Loans and research visits are commonplace among credited institutions and *bona fide* scholars.

Plant germplasm collections

Due to the traditional importance of agriculture and the extraordinary value of crop genetic diversity for food security and human health, plant resources have been collected for almost two centuries. The realization of the danger of losing these valuable resources has led to a great increase in the number of genebanks over the last two decades. In 1980, there were only about 54 genebanks, whereas today there are 1308, ranging from small, local stations that specialize in one or a few crops to international centers that contain over six million accessions representing thousands of species.

The single largest country collection is that of the US. The US collection is maintained by the National Plant Germplasm System (NPGS) of the US Department of Agriculture (USDA). This collection contains over 400,000 accessions representing 10,141 species from all over the world. In the 1970s international agencies created an international center to coordinate efforts between countries to collect, conserve, and allow for free exchange of crop germplasm. This center was called the International Board for Plant Genetic Resources, which later became the International Plant Genetic Resources Institute (IPGRI). Working through the Consultative Group on International Agricultural Research (CGIAR), IPGRI has collected over 200,000 accessions representing 4200 crop species and their wild relatives. This germplasm is stored in the 13 genebanks of the CGIAR system as well as in national genebanks all over the world.

Except for the holdings of private breeding companies, many government, international, and academic plant germplasm collections until recently practiced a policy of unrestricted access to qualified users, without regard for the cultural, geographic, or national origin of the genetic resources involved. This system worked under the premise that genetic resources of critical food crops must be preserved for the benefit of mankind and should, therefore, be available for improvement free of charge.²¹ According to some critics, however, since improved varieties can be subject to IPR laws, this system merely transferred genetic resources from developing countries to developed ones and increased the earnings of well-established breeding companies.²²

Existing *ex situ* collections need not comply with benefit-sharing arrangements because they were compiled prior to signing of the CBD, which is not retroactive. Additionally, the CGIAR centers are international institutes without exclusive national affiliations and are not subject to the terms of the CBD. A global fund has been proposed to capture and allocate some benefits from the plant breeding industry.²³ The FAO International Undertaking on Plant Genetic

Resources is a legally non-binding instrument that encompasses 159 countries and aims to facilitate access to plant genetic resources for food and agriculture. Since 1994, the Undertaking is being revised to comply with the CBD. The mechanisms for future benefit sharing include a possible multilateral fund or other financial arrangements through material transfer agreements (MTAs.) The Undertaking is also addressing the issue of benefit sharing derived from pre-CBD collections, such as the ones in CGIAR centers.

The CGIAR, which holds the largest germplasm collections of designated germplasm,²⁴ urged a halt to granting IPR for all materials they have provided, regardless of the date of provision.²⁵ CGIAR is also increasingly using MTAs, contracts on the conditions of transfer and use of genetic resources, particularly in the transfer of varieties, breeding lines, specimens and/or tissues with potential commercial significance. The MTA mechanism allows museums, herbaria, and collections in general to guarantee that genetic material does not inadvertently become subject to a private property regime. With traditionally academic institutions, such as the New York Botanical Garden, the Royal Botanical Gardens at Kew, and the Missouri Botanical Garden²⁶ arranging for the bioprospecting of their collections, MTAs play a critical role in sharing the benefits of biodiversity applications.

Repatriation

In addressing the control over genetic resources in collections, some people have suggested the repatriation of genetic samples and collections to the countries or communities of origin.²⁷ To the proponents, these requests are analogous to repatriation of art pieces stolen or seized during a war. There are, however, significant differences that weaken the analogy. Although modern art pieces usually have a straightforward traceable history, some genetic resources (e.g., plant varieties and domesticated animal races) are composites of multiple sources, often reflecting the convoluted history of human migration, displacement, and colonization. Furthermore, the communities or peoples that may have fostered a given landrace may no longer exist in a recognizable nucleus even in their country of origin.

The existence of *ex situ* collections is an obstacle to access regulations and constitutes a challenge for benefit sharing because these collections operate beyond the scope of the CBD, yet they house extremely valuable genetic resources from around the world.

DEFINING GENETIC RESOURCE OWNERSHIP AND TENURE

Assessments of genetic resource ownership are extremely complicated. Although it is relatively easy to determine ownership of a cow, or the production from a sorghum field, the equivalent operation for fungi, frogs, or previously undescribed plants is significantly more difficult. Part of the problem resides in the fact that knowledge of behavior, life cycle, yield, feeding habits, or distribution remains scant for most species, except for a few domesticated living organisms. To date, no scientist can claim to fully understand what a living organism is. Ignorance about genetic characteristics and potential is even greater. Furthermore, the subtleties embodied in terms such as "essentially biological processes," "non-biological," and "plant varieties" perplex the specialist and befuddle the legislator.

Only in the course of the last 150 years has humankind approached the biological endowment of the planet with a scientific explanatory framework to understand its richness and complexity.²⁸ Unfortunately, not knowing what an "essentially biological process" is does not prevent anyone from marketing it, regardless of the investment made by, for instance, a traditional community to discover, conserve, or improve the plant that nurtures it. Since property delimitation and evaluation of tenure are pivotal to the recognition and enforcement of property rights, the effective institutionalization of rights to genetic resources is an extraordinarily challenging task for policy makers.

Humankind, states, regions and locals: who shall inherit the earth?

The rights of ownership and tenure of natural resources have always been subject to dispute, with individuals, peoples, and nations willing to face wars if such an extreme measure seemed necessary. Genetic resources are not an exception, with further complications stemming from the lack of knowledge regarding living organisms, the widespread occurrence of certain species and processes, and the different levels of geographic jurisdiction over areas of endemism.

The CBD recognizes the sovereign rights of individual countries, with the national government in charge of assigning property rights over the resources.²⁹ Tenure and ownership systems, however, are not uniform across all countries, nor are they clearly defined in any given country. For example, legal systems in modern states can be divided between those subscribed to English Common Law and those founded on Roman Law. The first system views natural resources as private property, and the state has little participation in regulating access (but see Rose³⁰), whereas the latter system grants property to the state, holding natural resources as national patrimony.³¹ Based on this legislative heritage and each country's own cultural traditions, biodiversity-rich countries exhibit a mixture of ownership arrangements that range from traditional common tenure to state-enforced private rights to land and natural resources, including biodiversity.

The advent of globalization signals a new phase in regulation efforts as international cooperation accelerates due to improved communications. Hence, "global" initiatives propounded by agreements among signatory nation states constitute a hitherto unknown form of property regime where "humankind" is granted heritage of certain resources, e.g., designated germplasm.³² In the last decade this concept of "common heritage" has been eroded by the actions of industrialized countries, where strict IPRs are enforced, as well as concerns from underdeveloped countries, where biopiracy undermines the contribution of local communities to the conservation and improvement of genetic resources.³³

The WTO and the benefit-sharing goal of the CBD

There is a growing conflict between the World Trade Organization (WTO) and the CBD over intellectual property rights. The WTO Agreement on trade-related intellectual property rights (TRIPs) sets minimum standards and enforcement procedures for the protection of IPRs and requires signatories to recognize patents for most products and processes. Nevertheless, certain exceptions have been built into the TRIPs Agreement. Article 27.3(b) of the TRIPs agreement provides for the possibility of excluding "plants and animals other than microorganisms, and essentially biological processes for the production of plants and animals other than non-biological and microbiological processes" from patentability. Furthermore, "[i]nventions

dangerous to human, animal or plant life or health or seriously prejudicial to the environment" may be excluded under Article 27.2.³⁴

Patentability of life forms is a very contentious issue that has profound ethical, economic, environmental, and social implications. Indeed, Article 27.3 has proven to be highly controversial and is currently under review. Recently, there has been increasing pressure by industrialized countries to remove the Article 27.3(b) exception and require recognition of patents on plants and animals. However, many developing countries are arguing for the maintenance of the exception. For developing countries, the patenting of life forms has often led to the misappropriation of genetic resources and traditional knowledge by multinational corporations.

Conflict between customary tenure and legal property rights

Due to the intangible character of information and the cultural, social, and historical underpinnings of traditional communities often associated with the most diverse terrestrial ecosystems: forests. Defining who should regulate access or have rights to compensation arising from the use of genetic resources is a critical issue difficult to resolve.

In general, the ownership system applicable to property rights in developed countries is the product of historical patterns of industrialization, urbanization, and, to a certain degree, centralization. These systems are founded on individualism and optimum profit.³⁵ In developing countries, most traditional communities have continued to apply their own tenure system for biological resources, while the state enforces private and public property rights on goods and resources and mild IPR laws on industry and commerce. Many traditional tenure systems regarding genetic resources are grounded on collective ownership or heritage and, sometimes, religious and mystical considerations, particularly in the case of medicinal plants.³⁶

The agenda on ownership regimes in a given state need not coincide with the interests of communities therein—particularly traditional or indigenous communities or with provincial governments in federal states. In political systems in which traditional community tenure is not recognized through property rights, national governments may reward short-term gains in natural resource exploitation over conservation and long-term management in contested land. A network of tax exemptions, hidden subsidies in the form of roads and cheap wages, and/or property rights schemes that grant ownership only if forests are thoroughly felled has often facilitated such operations.³⁷ The economic development agenda that, until recently, prioritized intensive resource exploitation in order to achieve economic growth has been instilled into government institutions and officials for decades.³⁸ The mere inclusion of the term "sustainable" in official vocabulary is not sufficient to replace this self-defeating paradigm.

These kind of "modernizing" efforts have often encountered resistance from traditional communities, for whom the advance of market schemes represents a form of cultural and economic alienation.³⁹ The disputes over land tenure and agrarian reform that have occurred around the world throughout history are a stark example of this clash between government and traditional communities. Only in recent times have traditional communities been included in decision-making processes regarding genetic (and other) resources, which are often instated as state-owned or private property.⁴⁰ Nevertheless, traditional culture and knowledge are often

severely disrupted by contact with the market economy and community management gives way to extractive unsustainable exploitation under the pressure of burgeoning populations.⁴¹

Some countries, for instance Mexico and the signatories to the Andean Pact, assign tenure of biological resources to communities but reserve exclusive property rights for the state, thus limiting the distribution of benefits through a state-owned property regime while obligating communities to preserve the resources. How well these and other national regimes encompass the stakeholders in actual benefit sharing instances is yet to be evaluated. Similarly, how WTO signatories reconcile commercial interests with acknowledgement of traditional tenure of genetic resources is another lingering question.

In summary, the provincial, national, and international levels of political authority may subscribe to radically different assessments of ownership, which may also contrast sharply with some traditional community-based tenure systems. Since genetic traits that have been improved and conserved by humans, and naturally occurring characteristics cannot be easily distinguished, rightful assignment of property rights leading to benefit sharing becomes difficult to achieve.

INADEQUACY OF LEGAL, INSTITUTIONAL, AND SCIENTIFIC CAPACITY

Legal and institutional capacity

The complete absence of relevant legislation and institutional capacity has historically been an overwhelming handicap to the regulation of access in certain cases (e.g., Madagascar, see Box 1). In other post-CBD cases, the overlapping jurisdiction of various natural resource government agencies for managing genetic material becomes a problem in itself (e.g., Kenya).⁴² By now, sufficient literature has been compiled on the means and alternatives to install legal capacity;⁴³ Glowka's 1998 paper, in particular, reviews existing legislation extensively and develops a complete framework of legal guidelines at state and regional levels, also considering various stakeholders.

The development of legal and institutional frameworks for benefit sharing without properly installing communication mechanisms among the different levels of bureaucratic hierarchy may result in an exponential increase in access transaction costs (in time and cash), overwhelming the bureaucratic apparatus.⁴⁴ Implementation of access regimes is largely dependent on the political will and allocation of economic resources. The vast majority of developing countries are in fact constrained by their institutional and enforcement capacity. Therefore the formulation of regulatory mechanisms needs be grounded in a realistic assessment of the enforcement and control capacity of the state.

Dissimilar interests among national and provincial governments in federal states and overlapping jurisdiction of different government offices are factors that tend to make access to genetic resources burdensome. Increased access transaction costs coalesce with the wide disparities between institutional obligations and actual capacity to make enforcement difficult and costly. These complicating factors have become particularly acute with the advent of new genetic access regulations.

Box 1. The case of *Catharantus roseus*, the rosy periwinkle of Madagascar

Commonly known as the rosy periwinkle or Madagascar periwinkle, *Catharantus roseus* was originally used by Malagasy healers primarily in treating diabetes. In 1757, French explorers introduced this plant to the outside world, where it was used for curing sore throat, pleurisy, dysentery, and diabetes.⁴⁵ In the 1950s and 60s, the US National Cancer Institute undertook a large-scale effort to screen plants for anti-cancer properties, enlisting the help of Eli Lilly, a US pharmaceutical firm. Research scientists from Eli Lilly took an interest in the folk remedies from Africa and were intrigued by the association of the rosy periwinkle with treatment for diabetes. These scientists separated over eighty alkaloids from the leaves of the plant but found no cure for diabetes.⁴⁶

The screening process, however, did produce two compounds, vincristine and vinblastine, which were found to be powerful anti-cancer drugs. Vincristine is now used in treating leukemia, while vinblastine is effective in treating Hodgkin's disease and testicular cancer.⁴⁷ In combination with other medicines, vinblastine therapy achieves a cure rate of 80% for testicle cancer, formerly fatal in most cases.⁴⁸ Before 1957, childhood leukemia proved fatal to 95% of its victims. With the aid of vincristine, the survival rate is now 84%.⁴⁹ In 1983, the cure rate for cancer had risen above 50% in the United States for the first time in history,⁵⁰ and by 1985 Eli Lilly was raking in around US \$100 million annually from sales of these drugs, sold under the trade names Velban and Oncovin.⁵¹

The direct extraction of only an ounce of vincristine requires fifteen tons of periwinkle leaves and costs well over six thousand dollars. Small quantities are so effective, however, that only ten pounds of vincristine a year are employed in the United States.⁵² Records show that from 1979 through 1988, a total of 6629 tons of *Catharantus roseus* were exported from Madagascar.⁵³ During this period of time, it was necessary to gain approval from the CNARP in order to acquire an official permit for the exportation of medicinal plants. Apart from the joint effort made by CNARP, the Ministry of Commerce, and the Ministry of Agriculture to monitor the harvesting and exportation of *C. roseus* and other phylogenetic resources, no other regulatory mechanisms were in place. The absence of a national policy addressing issues of ownership and compensation has resulted in a loss of potential royalties from the sale of these medicines to the Malagasy people.⁵⁴

An additional conflict among institutions may arise when university departments, bioprospecting agencies, and scientific organizations develop research agreement protocols that include benefit-sharing provisions with local partners.⁵⁵ Since some nations are now developing and implementing their own access protocols, the questions arise as to how complementary these bilateral agreements are with respect to new regulations, and whether government agencies will honor agreements signed prior to state policy implementation.

Scientific capacity

Tropical countries harbor most of the world's undiscovered biodiversity. Currently, however, there is little infrastructure, few researchers, and practically no budget for basic biological research in most tropical, developing countries. Yet reliable access decisions need this research to define the scope, length, and sustainability of use of genetic resources. Enforcement of

regulated access regimes becomes impossible if such essential information as taxonomic or habitat identification is missing.

CONFLICTS OF INTERESTS AMONG STAKEHOLDERS

Until very recently exploitation of genetic resources generated benefits only for a few and sometimes in an unsustainable fashion.⁵⁶ As with every other valuable resource, different stakeholders have different priorities in their agenda for genetic resources. These different priorities might interact in a manner detrimental to regulating access, sharing benefits derived from genetic resources, or even preserving the biodiversity that supports it all.

Nation states

The CBD has established the authority of individual governments to determine access within their boundaries, stemming from sovereign rights over natural resources.⁵⁷ Ownership of genetic resources, however, remains a subject of national or sub-national regulation and hence varies from one state to the next. The purpose of Article 15 of the CBD is to redefine benefit flows that genetic resources generate because many developing countries perceived the previous *de facto* regime on access to be inequitable.⁵⁸

As an international initiative, the effectiveness of the CBD is contingent upon adequate national implementation and national capacity for enforcement. Hence, states have the largest role in benefit sharing through their particular regulatory frameworks and ownership regimes. In some cases, states are the ones to challenge misappropriation of genetic resources on behalf of traditional communities.

Nation states are sandwiched between the internal interests of traditional communities, provincial governments, and development objectives and the external interests pushing the enforcement of numerous multilateral agreements. The harmonious implementation (and enforcement) of regulations to satisfy these multiple and often contradictory objectives represents a major, perhaps intractable problem.

Local communities

Until very recently communities were viewed as "the refuge within which tradition lurks to trip progressive social trends."⁵⁹ Given that economic and social advancements are, after all, "the first and overriding priorities of the developing country parties" of the CBD, how did communities come to the forefront of the genetic resource conservation discourse?

Many programs for protecting the environment have failed precisely because cooperation from local communities was not sought or considered.⁶⁰ Insofar as certain genetic resources have been managed, preserved, improved, and used by local communities, the relevance of their role cannot be underestimated: communities often possess better information about their resources and may have greater capacity to enforce rules locally than external "experts."

Therefore, communities have become the focus of devolution of power, meaningful participation, and cultural autonomy. They are often empowered with biodiversity stewardship and assumed to possess inherently beneficial resource management skills.⁶¹ Following this

guideline, certain legislation drafts (e.g., Article 5.2 in the draft Organization of African Unity legislation proposal⁶²) stipulate communities as "sole custodians of the relevant knowledge, innovations and practices" arising from genetic resources "for perpetuity." Nonetheless, since programs to involve communities are still very new, no one can assess the validity of these assumptions or how effective communities will be in preserving and administering the genetic resources in the present global market.

With increasing self-awareness, communities in developing countries shall play a larger role in both the conservation of genetic resources and the implementation of benefit sharing. In its own turn, this decentralization accounts for a more plural, and somewhat more anarchic, international scenario, as communities negotiate benefit-sharing schemes directly with transnational parties.⁶³ It is also unclear how the dynamics of traditional authority systems will evolve within contemporary communities, as they face greater responsibilities and, presumably, greater rights.

Industry

Industry is perhaps the most powerful user of genetic resources, as it is capable of generating large cash profits. Channeling these benefits to other stakeholders is the formidable task of contracts, multilateral agreements, legislation, and all such access regulations. The use of genetic resources for development of agricultural and pharmaceutical products and processes is the *quid* of the commercial value of biodiversity. Interest from pharmaceutical industry is understandable since "57% of the top 150 brand names prescribed in this time period (January through September 1993) contained at least one compound now or once derived or patterned after compounds derived from biological diversity".⁶⁴

The huge expenditure—as much as \$231 million per new drug⁶⁵—in research and development might be rewarded by discovery of a marketable product. Before the CBD, the INBio–Merck agreement set the stage for bioprospecting investment,⁶⁶ and soon other companies followed the path of the genetic resource exploration. Pfizer, for instance, doubled Merck's US \$ 1 million upfront payment to INBio in an agreement with the New York Botanical Garden for drug leads from US plants.⁶⁷ New companies were created, like Shaman Pharmaceuticals and Andes Pharmaceuticals, which from the outset sought to share benefits with local stakeholders and, in the case of Shaman, incorporate traditional knowledge into prospecting schemes.

Despite advances in biotechnology that have erased barriers between varieties and species, significantly shortening the time needed to identify and incorporate desirable traits into crops, the agricultural industry owes practically all of its wealth to traditional farming, which originally domesticated all commercially important plants. Equitably sharing the benefits of millennia of seed exchange remains, however, a vexingly complicated issue that has no advocates in industry and few proponents in general.⁶⁸

The trend to increase coverage of patents across the board is (at least partially) fueled by the seed industry's interest. This change, however, might tend to further concentrate resources into a monopoly of few transnational corporations.⁶⁹ Furthermore, industry's overriding interest in profit limits research options as only a few crops for very narrow environmental conditions are improved,⁷⁰ and drugs are sought to suit the market for a few diseases with large markets in the developed world, e.g., cancer, and little else.⁷¹

NGOs

By raising concerns for disappearing forests and cultures, environmental NGOs have literally put biodiversity on the map for global policymakers. In many cases all the data available for assessing the state of genetic resources in a given area of the world comes from powerful environmental NGOs such as World Wildlife Fund for Nature, IUCN-the World Conservation Union, World Conservation Monitoring Centre, World Resources Institute, Wildlife Conservation Society, The Nature Conservancy, and Conservation International. They represent a new breed of international lobby with interests and objectives as diverse as the resources and communities they claim to defend.

NGOs have successfully leveraged their concerns into major international environmental conferences. In the current genetic resources debate, NGOs sometimes represent the interests of communities in denouncing violations against the CBD. As mediators and facilitators among different stakeholders, NGOs may lead bioprospecting initiatives,⁷² illustrate the clash between different international agreements,⁷³ or decry the incognizance of indigenous rights.⁷⁴

Scientists

The biological sciences are dedicated to the study of biodiversity, and, as such, they represent the source of much of the knowledge required to ensure its persistence. In addition, the vast and in-depth knowledge held by local people should not be overlooked by scientists and conservationists. The current state of knowledge, however, is precarious. There is no accurate appraisal of the number of species on the planet or a reliable comparison between current extinction rates and pre-human ones. Recent studies tend to debase the efficiency of certain taxonomic groups as "indicators" of overall diversity,⁷⁵ making the assessment of biological diversity even more burdensome.

A global inventory is urgently needed to prioritize areas and taxonomic groups for conservation.⁷⁶ This task, however, requires human and economic resources that are well beyond current global scientific capacity. Nonetheless, numerous professional associations have publicly advocated efforts to chart the biosphere and improve knowledge of the relationships among organisms and between them and their environment. This type of work, however, requires the use of samples and collection of specimens, which constitutes a form of access to genetic resources.⁷⁷

Like NGOs, scientists have contrasting interests that reach beyond the scope of this overview. Restrictions on access, however, affect routine activities connected to basic research in ecology and evolutionary biology as tissue samples, whole specimens, and other such biological materials become the subject of intricate and costly bureaucratic procedures. Hence, the case for more expeditious implementation of access regulations and less restrictive legislation for pure research has been made by concerned conservation biologists.⁷⁸

Unless otherwise stated by the access applicant, a clear method for objectively distinguishing commercial and basic research interests in access regulation does not exist. As mentioned earlier, the distinction is unclear because academic institutions may be committed to commercial research requiring collection of genetic resources. Furthermore, there is a continuum of research

aims ranging from purely academic or basic science to commercial bioprospecting. These goals may not be clear from the start of collection agreements. Additionally, commercial applications are almost invariably based on information obtained through basic research, which further blurs the line between the two activities. Commercial applications of genetic resources acquired for academic purposes are often fortuitous and cannot be entirely foreseen by the stakeholders involved, creating uncertainty in the process of applying access regulations.

Regulatory frameworks need to circumvent the obstacles reviewed here. Some of these obstacles can be addressed in the context of national regulation, others may require regional cooperation within the CBD framework, and yet others are inherent to genetic resources and may not be as successfully approached at any level. The challenge to access regulation and benefit sharing that these obstacles pose is key to constructing more effective access regulations and evaluating existing ones. The cases examined in this paper exemplify some ways in which regulation has overcome these obstacles with various degrees of success.

CHAPTER III. ACCESS TO GENETIC RESOURCES: CASES

National governments, private companies, non-governmental organizations, and research institutions have attempted to overcome, with varying degrees of success, the obstacles discussed in Chapter II. Prior to the CBD, private genetic resource access agreements were negotiated on an *ad hoc* basis. However, the ratification of the CBD has required greater involvement by national governments including the development of regulatory frameworks to govern the formation of future genetic resource access agreements.

In this chapter, seven different genetic resource access agreements are described and analyzed. These seven cases were selected from preliminary research that was done in preparing for this report. The countries and regions that we examined were Fiji, Sarawak, Indonesia, Colombia, Cameroon, Nigeria, Suriname, India, Philippines, Brazil (at the federal and state level), Belize, Ethiopia, Kenya, Costa Rica, and the Hopi Reservation in the United States Southwest. We assembled profiles of these regions that included information about the parties involved, the ecosystems of the regions, the regulatory environment, and potentially contentious issues. The data we collected describes various treatments of benefit sharing, prior informed consent, local knowledge, sustainable use, and conservation.

We selected the seven case studies presented below based on several criteria including availability of information, relevance to the CBD, time constraints, as well as the familiarity of our workshop members with specific projects or geographic regions. Most regions of the world and a variety of stakeholders including private actors, non-governmental organizations, research institutions and governments are represented. The case studies also represent a broad array of regulatory environments. On one end of the spectrum, we examined an agreement in Cameroon, a country that currently has no regulations governing access to genetic resources. We also examined cases in Costa Rica, Fiji, and the US, countries that have already-established laws impacting access to genetic resources, but have yet to ratify legislation specifically designed to comply with the goals of the CBD. Furthermore we analyzed an agreement in a country, Brazil, that is currently considering proposed AGR legislation. On the other end of the spectrum, we examined two cases in countries that have adopted legislation specifically designed to comply with the goals of the CBD. We examined a case in Colombia, a country that has signed a regional agreement governing access to genetic resources, but has not yet proposed domestic legislation for implementing the agreement. Finally, we analyzed agreements in the Philippines, a country that has developed comprehensive legislation for regulating access to genetic resources.

The following questions were developed in order to analyze the seven case studies in light of the stated goals of the CBD:

- How are stakeholders identified and represented?
- How are property rights addressed?
- How is prior informed consent (PIC) ensured?
- How are benefits distributed?
- Do the terms of the agreement encourage compliance and are there mechanisms in place to handle disputes?

- How are sustainable development and conservation addressed?

These questions form the general framework from which we analyze the specific elements common to successful genetic resource access agreements and legislation.⁷⁹

THE INBIO–MERCK RESEARCH AGREEMENT IN COSTA RICA⁸⁰

The agreement between the National Biodiversity Institute (INBio), and Merck & Co., Inc. (Merck) is perhaps the most widely recognized and discussed bioprospecting effort in the world.

INBio is a Costa Rican "non-government, non-profit, scientific research institute of social orientation and for the public good."⁸¹ It was officially created on 25 October 1989 (three years prior to the CBD) on the recommendation of a National Planning Commission. Its four main objectives are (1) to assume responsibility for developing and executing a national biodiversity inventory, (2) to locate national collections within one physical space under a single administration, (3) to centralize biodiversity information, and (4) to put information on biodiversity in easily understandable form for a wide variety of users and promote its use by Costa Rican society. The operation of INBio is overseen by a General Assembly composed of 21 members from diverse backgrounds, six of whom form the Board of Directors. Although INBio's agreements with private companies such as Merck have occupied the spotlight, only 15% of INBio's total yearly budget is derived from such agreements; the remaining 85% is obtained through project grants from a diverse array of sources.⁸²

Although INBio is an NGO, it enjoys a special relationship with the Ministry of Environment and Energy (MINAE⁸³), formalized in their Cooperation Agreement signed 7 October 1994.⁸⁴ The INBio–MINAE agreement is valid for a period of five years from the date signed, and is automatically renewed for the same period. This agreement begins by reviewing relevant existing legislation in 14 Precedents and goes on to stipulate the details of the relationship between INBio and MINAE in 13 Clauses. Important clauses include Clause 1 which establishes that INBio and MINAE will work together on the national biodiversity inventory while expressly prohibiting the commercialization of samples taken for the purpose of the inventory; violation results in severance of the agreement and application of the Wildlife Conservation Law. However, Clause 8 stipulates that MINAE is to allow INBio to collect biological samples for the purpose of bioprospecting. Clause 11 states that the equivalent of at least 10% of each bioprospecting venture's budget is to support the management and protection of Conservation Areas.⁸⁵ Finally, Clause 12 establishes that 50% of any economic and material benefits INBio receives through bioprospecting are to be transferred to MINAE, and it further stipulates that they will be "exclusively invested in management and conservation of wildlands administered by [MINAE]."

Merck is a research-driven multinational pharmaceutical products and services company, organized under the laws of the State of New Jersey, USA.

The agreement between INBio and Merck was first signed on 1 November 1991, and it was subsequently renewed on July 1994 and August 1996. INBio's purpose in establishing the

agreement is to collaborate with private industry to create mechanisms to help maintain Costa Rica's Conservation Areas by making them economically viable; Merck is interested in obtaining genetic material for pharmaceutical and agricultural development. The agreement includes a confidentiality article (Article 9) which prevents either party from disclosing any "Confidential Information" to third parties for a period of seven years⁸⁶ from the expiration of the agreement; consequently, a number of important data were unavailable for our analysis, such as the division of net royalties between INBio and Merck.⁸⁷ For its part, INBio stipulates in Article 3(c) that 50% of any royalties it receives are destined for MINAE, in accordance with their agreement.⁸⁸ Merck provided \$1 million during the first two years for the purchase of laboratory equipment and materials to operate INBio's processing laboratory; the original agreement establishes that Merck is to provide additional funding in an agreed amount for the extension period. The agreement applies to the sharing of a predetermined (confidential) number of plant, insect, and environmental (microorganism) samples. Samples are initially extracted and processed by INBio, and their properties are explored at Merck facilities in Spain and the US.

The agreement is renewed every two years. Although Article 7 of the standard INBio Collaboration Agreement specifies the non-exclusivity of the arrangement, the contract with Merck prevents INBio from supplying other organizations interested in human and animal health or agriculture with the samples it provided Merck for a two year initial evaluation period. After the two year evaluation period, Merck may extend the exclusive evaluation period indefinitely for up to 1% of the total number of samples provided to them. INBio is free to offer all other samples to other parties and is similarly at liberty to enter into agreements with other parties. Indeed, INBio has forged partnerships with a number of parties from the national and international academic and business sectors.⁸⁹

REGULATORY ENVIRONMENT

The regulatory environment is summarized in the Precedents of the first part of the INBio–MINAE Cooperation Agreement. In addition to the laws discussed therein, Law 7788, the Biodiversity Law of Costa Rica, is pertinent.

STAKEHOLDERS

The primary stakeholders identified in the INBio–Merck agreement are INBio and Merck. However, MINAE is also cited several times. Although they are not mentioned explicitly, private property owners are implicitly treated as stakeholders both by the agreement and Law 7788 in terms of the physical tenure of genetic resources. The agreement does not identify any other stakeholders.

The INBio–MINAE agreement identifies additional stakeholders, recognizing (in the Third Precedent) the rights of "Costa Rican and foreign nationals to practice scientific and cultural activities of animal and plant collection, of their products and byproducts, and to carry out investigations, as long as they do not violate this Law [7317 of 7 December 1992, Article 36] and its regulations." Consequently, other individuals and organizations are not prohibited from using biological resources.

In addition to the State in all its manifestations, Law 7788 identifies local communities, indigenous peoples, scientists, and academic (particularly universities) and scientific organizations. In particular, Article 83 calls for the participation of local and indigenous communities in establishing *sui generis* community intellectual property rights.

PROPERTY RIGHTS

Tangible property

Exactly who is granted ownership of the physical resources is unclear. The INBio–Merck agreement stipulates that samples will be collected from "the Conservation Areas of Costa Rica and other areas of the private domain."⁹⁰ As specified in Article 28 of Law 7788, Conservation Areas fall under general supervision of MINAE. They include protected wildlife areas, areas with a high degree of fragility, and private areas with commercial exploitation, and MINAE is responsible for establishing the division of national territory into the "technically most recommendable" Conservation Areas. Furthermore, Article 6 of the law states that biochemical and genetic property of wildlife and domesticated breeds belongs to the public domain, and grants the State the power to authorize its exploration, investigation, bioprospecting, use, and exploitation.⁹¹ Article 76, however, refers to the "private property owner who provides the elements to be accessed" as being entitled to compensation.⁹² In summary, no mention is made of the "owner" of the physical resources in either Costa Rica's legislation or the INBio–Merck agreement. A loose interpretation of the language of Article 28 and the INBio–Merck agreement would appear to grant INBio and, consequently, Merck, access to all biological resources⁹³ found within Costa Rican territory. Similarly, Articles 65 and 76 of the law and the first paragraph of the INBio–Merck agreement imply that arrangements must be made with private property-owners from whom access to physical resources is sought, but they are clearly not granted ownership rights. Article 76 of the law specifies that the Technical Office of the Commission of Biodiversity Management is to authorize all contracts and agreements relating to biodiversity, whether they are among private individuals or institutions.

Intellectual property

The INBio–Merck agreement is explicit in its treatment of patents, marketing, and licensing. Each party is authorized to independently prepare, submit, follow-up, and maintain all patents, provided they consult the other party on all plans and developments. The agreement does not address intellectual property rights of any other stakeholder. However, it does conform to the environmental laws of Costa Rica.

Section 3 of Law 7788 deals with intellectual and industrial property rights. Article 78 identifies six mechanisms of protection: patents, commercial secrets, plant improvement rights, *sui generis* community intellectual property rights, author's rights, and agricultural rights. Seven exceptions are also listed; those most important in the present discussion are (1) DNA sequences *per se* and (6) inventions derived from knowledge associated with traditional or cultural biological practices in the public domain. This latter point (6) juxtaposes with Article 82 (*sui generis* community intellectual property rights) which stipulates that the State expressly recognizes and protects the practices and innovations of indigenous peoples and local communities. As expressed in paragraph two of Article 82, the purpose of the article is to prevent any form of protection of intellectual or industrial property rights from affecting historical practices; it does not constitute

a recognition of any property rights *per se* or mandate compensation. Articles 83 and 84 call for the examination, determination, and registration of *sui generis* community intellectual property rights via a participatory process; Article 85 calls for the determination of how *sui generis* community property rights will be used and who will hold their title, and will identify the recipients of any benefit derived therefrom.

PRIOR INFORMED CONSENT

Article 4(a) of the INBio–Merck agreement requires that INBio obtain written prior informed consent from Merck before entering into an agreement with a third party with regard to a product developed by Merck, and 4(b) recognizes that a party may refuse to give its consent. Although prior informed consent is often not named directly in the Collaboration Agreement, the agreement requires that virtually all developments be reported to the other party. For example, Merck must notify INBio of any sublicensing agreements involving INBio samples or confidential INBio information. Merck is similarly required to inform INBio of the discovery of any bioactive compounds detected in INBio samples. In certain occasions, such as Article 5(D) on patenting, the agreement requires that parties consult with one another about the preparation, application, follow-up, and maintenance of patents; although language is somewhat vague this implies the requirement of prior informed consent and mutually agreed terms. No reference is made to obtaining prior informed consent from non-parties (except for the acquisition of required State collection permits). The INBio–MINAE agreement does not address prior informed consent regarding non-parties either, although it does clearly establish that INBio must inform MINAE of the handling techniques to be implemented before collecting samples (Clause 8).

Law 7788 explicitly addresses prior informed consent in Article 65, as it concerns obtaining "access to elements of biodiversity." In cases involving access to resources on private property, the Technical Office of the National Commission for Environmental Management must be provided documented proof of the land owner's prior informed consent. If indigenous lands are involved, prior informed consent must be obtained from the authority of the indigenous community and the Director of the Conservation Area. Article 66 recognizes local and indigenous communities' right to oppose the access to resources and associated knowledge for cultural, spiritual, social, economic, or any other reason. Article 80 requires that the Nation Seed Office and the Registry of Intellectual and Industrial Property be consulted prior to establishing protection of the intellectual property of industrial innovations; it also requires that the original certificate of origin and proof of prior informed consent be submitted with the documentation.

DISTRIBUTION OF BENEFITS

As mentioned above, Merck provided US \$1.0 million during the first two years for the purchase of laboratory equipment and materials to operate INBio's processing laboratory. The details of subsequent financial arrangements related to agreement extension are unavailable, as is the specific portion of net royalties to be received by INBio. As per their agreement, INBio provided MINAE with US \$100,000 (10% of budget) for reinvestment in conservation. No royalties have yet been derived from INBio samples. No other benefits are reported to have been distributed as part of this agreement.⁹⁴

COMPLIANCE MECHANISMS AND CONFLICT RESOLUTION

The INBio–Merck agreement encourages compliance primarily by requiring frequent and open communication among the parties. Several articles⁹⁵ include provisions for communication and exchange of information; this is best exemplified by the spirit of Article 2, which requires that project directors realize informal consultations in person and by telephone regarding the management of the agreement and must regularly exchange the results of research and technical knowledge. Explicit compliance mechanisms involve only the payment of royalties. Article 3(d) states that if an audit discovers that an unfair payment in excess of 10% has occurred, the erring party must pay the full cost of the audit and correct the amount paid as soon as possible.

Article 10(j) of the INBio–Merck agreement provides an explicit mechanism for resolving conflict, in which mutually agreed terms are sought. The mechanism consists of three phases that begin by attempting to resolve disputes through discussions in good faith. If after two months the conflict is not resolved, the matter is passed to a single high ranked official of each party. If they are unable to reach agreement after four months, the issue is to be decided upon by an arbiter. If this fails, either party may initiate a judicial process.

The INBio–MINAE agreement also encourages compliance through mutual participation and frequent communication. Clause 1 requires that the parties work together on the national inventory and that INBio allow access to its collections by the public and State authorities. Clause 5 stipulates that INBio must supply technical assistance in the evaluation of projects and other conservation activities, and requires that INBio conduct training sessions for MINAE officials. Clause 7 states that INBio is to provide MINAE with a list of the personnel INBio has authorized to conduct research. Clause 9 allows MINAE to supervise and audit INBio's activities and requires that INBio submit any detailed reports requested by MINAE. Clause 1 is unique in stipulating the penalties to be applied in the event that samples collected for the national inventory be commercialized, and this is reiterated in Clause 8. No other compliance mechanisms are stipulated in the agreement.

Chapters VIII and IX of Law 7788 provide a number of compliance mechanisms. Chapter VIII includes seven articles that stipulate specific and general incentives. However, these are primarily oriented toward sustainable development and local and indigenous communities, and only affect the INBio–Merck agreement indirectly, if at all. Chapter IX addresses the issue of sanctions and non-compliance procedures. Of particular interest in the current discussion is Article 112 on unauthorized access to elements of biodiversity; this article stipulates that parties who access biodiversity without permission or in a manner inconsistent with the stated purpose will be subject to a fine of between one and 12 salaries.

CONSERVATION AND SUSTAINABLE USE

The INBio–Merck agreement does not explicitly address sustainability. As related to their practices, sustainable use is most explicitly by Clause 4 of the INBio–MINAE agreement, which states that "INBio's gathering of specimens will cause no harm or alteration that may imply or become a threat to the biodiversity of the site where the specimen was removed."⁹⁶ Law 7788 addresses sustainable use in Chapter IV, but most of the text is only marginally applicable to the

INBio–Merck agreement. Article 49 has the most bearing on INBio–Merck activities, but is limited to identifying the protection of biological processes as a State duty and outlining some mechanisms to accomplish this, including environmental impact studies, permits, and licenses.

INBio's primary goal in establishing the agreement with Merck is to support conservation through commercial exploitation of genetic resources. The direct effect this has had on conservation has been the infusion of \$100,000 into MINAE coffers to support the maintenance of Conservation Areas. Furthermore, and perhaps more importantly, INBio's Merck-supported activities help increase public awareness and appreciation for biological resources.

CONCLUSIONS

INBio and Merck crafted their agreement fully aware of both the staggering potential payoffs and the long-term commitment and expense of bioprospecting. According to their own assessment, only one out of 10,000 samples proves to be commercially viable, and it may take 10–15 years for a product to reach the market after discovery, making bioprospecting an extremely risky venture. In light of these facts, for INBio it was essential that they receive an up-front payment to be able to build their facilities, initiate work, and provide MINAE with an infusion of cash to enhance its conservation activities. Rather than focus exclusively on "green gold" payoffs, they emphasized scientific and institutional capacity building. Merck, in turn, required access to samples and reliability.

The INBio–Merck agreement, as it articulates with the INBio–MINAE agreement and Law 7788, provides an excellent example of an attempt to overcome the obstacles outlined in Chapter II. The strategy of having a pair of overlapping agreements—one between the state and the national organization, and the other between the national organization and the foreign organization—is particularly effective in reducing the number of parties in each negotiation while ensuring that their interests will be considered by all parties. For example, by participating in the Special Mixed Subcommission that developed Costa Rica's Biodiversity Law, INBio was able to ensure that the new legislation did not jeopardize the agreement with Merck. The INBio–Merck agreement attempts to increase institutional capacity by providing MINAE with a large infusion of cash, and increases scientific capacity through technology transfer and training. Furthermore, many of INBio's activities focus on public education, and these would not be possible were it not for INBio's bioprospecting activities.

However, any evaluation of this agreement must be tempered by three concerns. First, no specific measures have yet been taken to ensure that local and indigenous property rights are enforced and communities compensated. Article 85 of Law 7788 could lead to explicit legislation, but no measures have been taken thus far. Second, because no economically exploitable substances have been identified yet, it is impossible to evaluate the efficacy of the agreement in terms of the distribution of benefits. Third, the confidentiality clause in the INBio–Merck agreement prohibits the public release of a number of important details, such as the division of royalties between Merck and INBio. The way in which the US \$1 million up-front payment was effected and subsequently distributed is reason enough for optimism; but that portion of the arrangement was necessarily transparent, whereas the way discoveries are dealt with leaves much more room for interpretation and disagreement.

THE NCI–UNIP AGREEMENT: BIOPROSPECTING IN BRAZIL UNDER A DEVELOPING REGULATORY ENVIRONMENT⁹⁷

The National Cancer Institute (NCI)–Universidade Paulista (UNIP) agreement is in its initial stages of development. It constitutes an interesting case because it has been proceeding in the midst of the development of state and federal AGR legislation in Brazil. It also involves an innovative type of collaborative agreement that has proven useful in other cases. This agreement is examined below, after a summary of the regulatory situation in Brazil and in the State of São Paulo.

REGULATORY ENVIRONMENT

Prior to the CBD, access to Brazilian genetic resources, derived products, and associated traditional knowledge was unregulated for Brazilian nationals except for the export of materials. Regulation of collection of biological materials by foreign researchers in Brazil was established in Decree 98.830 of 15 January 1990; applications for research permits are processed by the National Council for Scientific and Technological Development (CNPq). This decree dictates that foreign scientists are authorized to conduct research only in coordination with a recognized and competent Brazilian institution. Other requirements are that foreigners supply information on the source of financing of the project, agree to allow the Brazilian Ministry of Science and Technology to publish the research, and agree to conditions limiting export and commercial exploitation of any collected materials. One limitation of the decree is the absence of protection for indigenous or traditional knowledge.

Following Brazil's ratification of the CBD in 1994, concern mounted around implementing laws to comply with principles of the articles of the Convention relevant to the issue of access to genetic resources and the fair and equitable sharing of benefits derived from this access. There are several federal bills presently being discussed in the Brazilian Congress, and they constitute the first legislative documents on the issue of access to genetic resources. At this time, the states of Amapá and Acre have passed legislation regulating access, and São Paulo is developing legislation.

São Paulo State

From 1995 until 1997, the Environmental Secretariat of São Paulo State (SMA) automatically denied all requests for access to genetic resources without further discussion due to a lack of capacity to address them appropriately. State officials were also anticipating a decision on federal access legislation.⁹⁸ Access requests made since 1997 are still under consideration.

Prior to 1995, access to biological resources was unregulated at the state level. In 1995, the state's recognition of its obligation regarding biodiversity protection and to the precepts in Agenda 21 and other international conventions, coupled with several requests for access to resources in state Conservation Units, stimulated the creation of the São Paulo State Biodiversity Programme (PROBIO/SP) within the SMA. This program, led by an interdisciplinary team, aims

to integrate the interests of different stakeholders, internal and external to the SMA, and to discuss biodiversity-related issues currently in debate.

On 6 January 1999, the SMA issued Resolution 001-99, which aims to establish more control over the nature of research and bioprospecting endeavors until specific legislation is enacted. This resolution defines mutually agreed terms that must be signed by researchers requesting to collect on state land, as well as by those already involved in research projects in these areas. It mandates the elaboration of a São Paulo State law by an interdisciplinary working group coordinated by PROBIO/SP. A bill has been drafted (*Minuta de projeto de Lei, 7a versão*, SP Bill) which elaborates on the agreed terms laid out in SMA Resolution 001-99 along with many other issues regarding access and benefit sharing. An important point in the state bill is that research permits are issued primarily for non-commercial collection of material. Any potential for commercial development must be addressed in a further agreement with the state. If passed, the law would replace SMA Resolution 001-99. The SP Bill is currently being discussed in various public fora and a final draft has not yet been presented to the state government.

The SP Bill establishes that authorization for access to genetic resources, derived products, and traditional knowledge will only be granted to a Brazilian institution, public or private, conducting biological research. Foreign researchers will be authorized to conduct research only in conjunction with an authorized supervising Brazilian institution (Article 10).

Federal level

A first attempt to establish equitable benefit sharing in regulation was the proposal of two amendments to a federal patent bill in debate, authored by Senator Marina Silva, which specifically addressed the rights of indigenous populations and local communities whose knowledge, innovations, or practices are used in product development. While the patent law was passed in 1996, the Senate rejected the Silva amendments, instead relying on the international standards of the Uruguay round of the GATT/TRIPs agreement relevant to indigenous populations and local communities.

Work on this issue currently focuses on the debate in the National Congress of three proposed federal bills regulating access to genetic resources and their derived products, the protection of associated traditional knowledge, and the sharing of benefits derived from resource use.

The first of these is National Bill No. 306, introduced in October 1995 by Senator Silva.⁹⁹ Bill No. 306 specifically and comprehensively addresses the issue of national sovereignty over genetic resources (Article 5), the regulation of access to these resources and their derived products (Articles 14 through 34), the protection of traditional knowledge associated with genetic resources (Articles 44 through 47), and the sharing of benefits derived from the outcome of access to genetic resources (Articles 35 and 36), as described in the CBD. If ratified, this piece of legislation would require that access to genetic resources and the sharing of benefits derived therefrom be controlled by a single national agency, the "competent authority," to be named by the Executive Power. The competent authority will have the power to grant authorization for access, monitor requests for and activities of access, grant authorization for and monitor the export of samples, as well as maintain a database of information and requests for access and remittance.

Nevertheless, some concerns about Bill No. 306 were raised by various NGOs and the Worker's Party. To address them, Representative Jaques Wagner introduced a second bill in the Lower House in June 1998, differing on several points from Bill No. 306. The main difference is that the Wagner bill affords stronger rights to indigenous peoples and traditional communities by referring to laws which enable other entities to act in defense of these groups' rights.¹⁰⁰

A third bill has been prepared by the Interministry Group on Access to Genetic Resources (GIARG). This group was established by the Executive Power in 1996 to review and analyze Bill No. 306. In the same year, the Ministry of Environment organized a National Workshop to present and discuss Bill No. 306 inviting government officials, including GIARG, public institutions, and NGOs. After two years of study GIARG put forth their bill to the National Congress, a bill "significantly more concise" than Bill No. 306.¹⁰¹ The group recognizes the urgency of the matter given the rapid advances in the fields of biotechnology and bioprospecting and the ever-broadening scope of information sharing across the globe. The bill at once proposes to control access to patrimonial resources while promoting the development of legal bioprospecting activities through authorizing only national institutions, public or private, for access to genetic resources. Foreign institutions or researchers may conduct bioprospecting and research only through association with a national public institution.

Additionally this group proposed an amendment to Article 20 of the Federal Constitution so as to include genetic resources among the "goods of the Union," which already include mineral and natural resources named in other parts of the same article. The bill and the constitutional amendment together would establish regulations of access to genetic resources and associated traditional knowledge, and the sharing of benefits derived from their utilization.

The major difference between the GIARG bill and the No. 306 and Wagner bills is in the scope of the legislation. The GIARG proposal is of a more generic nature leaving the specific details of regulation, such as the Terms of Responsibility, to be developed and implemented via regulatory mechanisms yet to be established. Alternatively, the No. 306 and Wagner bills clearly define the protocol for request for access and contract.¹⁰² These different approaches raise the fundamental question of how much legislation is necessary to implement the goals of the CBD relevant to access to genetic resources.¹⁰³

Another difference between the two bills relates to benefit sharing. Article 11 of the GIARG bill states that benefits from the economic exploration of a product or process resulting from access to patrimonial genetic resources must be shared in a fair and equitable manner with the Union, comprising indigenous or local communities, national, state, municipal, or private owners—in a percentage defined in further regulations. These benefits are defined in Article 12 as royalties, technology transfer, licensing of products and processes, and human resource training. The No. 306 and Wagner bills, on the other hand, deal with benefit sharing and compensation in various articles and in less concise terms.¹⁰⁴ As defined in Article 4 of these bills, benefit sharing refers to the "distribution of outcomes, whether economic or not, of research, development, commercialization or licensing derived from the access to genetic resources."

The atmosphere of uncertainty that results from pending legislation on access to genetic resources does not lend itself well to the establishment of access agreements, either for national or foreign research. Nevertheless, the NCI–UNIP agreement has moved forward and a request for access has been posed to the state by UNIP.

The NCI–UNIP and UNIP–SMA Agreements

NCI is a component of the National Institutes of Health, one of eight agencies that compose the Public Health Service in the Department of Health and Human Services. Established under the National Cancer Act of 1937, the NCI is the principal agency for cancer research and training for the United States Federal Government. An additional 1971 Act broadened the scope and responsibilities of NCI and created the National Cancer Program, which conducts and supports research, training, health information dissemination, and other programs with respect to the cause, diagnosis, prevention, and treatment of cancer. For this purpose, NCI supports and coordinates research projects conducted by universities, hospitals, research foundations, and businesses throughout the US and abroad through research grants and cooperative agreements. UNIP is a private educational institute in the State of São Paulo, Brazil.

Access to Brazilian resources by NCI is structured as a two-part process. A request for authorization of collection and commercialization is made by in-country actors to state and federal authorities, while an agreement is negotiated between the foreign and source-country scientific institutions regarding technology and material transfers as well as screening for bioactive compounds. In mid-1997 UNIP and NCI signed an agreement following the standard format of NCI's Memorandum of Understanding (MoU) and are currently collaborating in bioprospecting research.¹⁰⁵

UNIP additionally submitted a request for access to genetic resources to the SMA in July 1997. In the proposal they requested permission to collect plant samples at the Intervales State Park, one of the largest remnants of Atlantic Forest in São Paulo. The SMA rejected the proposal stating that its relevance to the country and state was diminished by the fact that bioprospecting for tropical diseases was not included, and that it did not involve any public research institutions. UNIP has since submitted a new request, this time in association with two public institutions, *Universidade do Estado de São Paulo* (USP) and *Universidade Federal do Estado de São Paulo* (UFESP), and expanded its objectives to include bioprospecting for tropical diseases like leishmaniasis, in addition to cancer and AIDS.¹⁰⁶

If the UNIP–USP–UFESP group signs an agreement with the SMA they will obtain collecting permits for the State Park. The terms of the SMA Resolution, however, explicitly prevent researchers from using the samples for commercial purposes unless authorization has been given by the national competent authority and the SMA, and maintains that this can occur only once federal legislation is established. This means that until federal legislation is passed researchers could screen the samples and conceivably proceed with all stages of drug development except for patenting and commercialization.

STAKEHOLDERS

The parties identified in the NCI–UNIP MoU are the United States Government, represented by NCI, and the organization in the source country, UNIP. Although not specifically addressed in the MoU, those with property rights over the land where resources are collected are stakeholders in this agreement. When collection is requested in state Conservation Units, the São Paulo State Government is also a stakeholder.

Several traditional communities live within state lands.¹⁰⁷ As communities with traditional tenure over this land and providers of traditional knowledge they can also be considered stakeholders but are not mentioned in the MoU. They would be explicitly considered, however, under a UNIP–SMA agreement, although their degree of involvement would depend on the state regulatory element used. Resolution 001-99 is more vague, stating that collectors are to respect the CBD terms regarding traditional knowledge. The SP Bill, however, states that SMA will require proof of prior informed consent from these communities if traditional knowledge is to be accessed, and participation of traditional communities and indigenous populations in decisions regarding access to resources in areas occupied by them (Article 1, IX). They are considered one of the necessary parties to the benefit sharing contract, as outlined in Article 17. This bill also acknowledges that native genetic resources and derived products are of relevant public interest (Chapter I, Article 1). Since the proposed collecting activities are restricted to state land, private landowners are not direct stakeholders in this case.

All three federal bills recognize the Union as holding sovereignty over genetic resources and their derived products existing in Brazilian national territory. Parties to the contract for access as named in Article 19 of the No. 306 and Wagner bills include (1) the State, (2) the petitioner of access, and (3) the provider of traditional knowledge or domesticated crop if the case of access involves these components. Other parties may be named in additional contracts. These bills propose that the holders of intellectual property rights be determined in the access contract.

The GIARG bill requires a legally binding, multilateral Contract of Utilization of Genetic Resources and of Benefit Sharing that clearly states the parties involved. These are: (1) the Federal Union represented by the competent authority, (2) the appropriate land owner or representative of an indigenous community or local community, (3) the national institution authorized for access, and (4) the institution to which the product or process is destined.

PROPERTY RIGHTS

Tangible property

Bill No. 306 states under Article 2 that "genetic resources and derived products are considered public property for special use of the Brazilian Nation" and recognizes the national sovereignty over genetic resources in Article 5. The proposed constitutional amendment, however, would be a binding declaration of national ownership of genetic resources. Some feel that the amendment presents the best solution to ownership conflicts.¹⁰⁸

In São Paulo, provisions regarding property rights of the land or biota where the genetic resources are to be collected are not provided in the MoU between NCI and UNIP. Rather,

property rights are addressed in the agreement between the source-country organization signing the MoU and the state, in this case UNIP and SMA. UNIP has requested access to only the Intervalles State Park for random collection of higher plants; thus property rights pertaining to state land apply, according to the proposed state law. An attempt to clarify the legal rights of those traditional communities with tenure of state land is currently under way.¹⁰⁹ UNIP is currently going through the Resolution 001-99 permit application process, which does not include these communities in its provisions. Clearer regulatory guidelines regarding access to tangible resources will arise once the UNIP–SMA agreement is established.

According to the SP Bill, regulation of resources on private property are to be dealt with under federal provisions on property rights, and the regulation of access to lands owned by indigenous populations is deferred to specific legislation and is explicitly excluded from the state law provisions. It further states that it does not intend to interfere with the rights of the owners of that land where the resources are found. Under its premises, private owners are free to negotiate payments (compensatory or royalty-derived) directly with the users, federal procedures and fees notwithstanding.

The GIARG bill specifically recognizes the different land property types including indigenous lands, protected areas, private property, and areas indispensable for national security, each of which has an organizing body that must be a party to the contract for access.

Intellectual property

This type of NCI agreement provides for joint patent protection for all inventions developed collaboratively by the NCI and source country employees. Moreover, if a compound isolated in the source country merits advancement to pre-clinical development, the source country can elect to apply for patent protection as the sole owner of the invention. All licenses for commercialization on patents arising out of this collaborative agreement refer to the agreement. Regarding traditional knowledge, the MoU terms seem to rely on the source country's internal arrangements for regulation. The federal bills currently proposed differ in their treatment of traditional knowledge, so the outcome of the senate deliberations could affect the strength of this provision in the São Paulo State law.

Under the current SP Bill, permission to patent any product or process obtained from the access to resources in State Conservation Units is to be regulated by the state (Article 19); in private areas however, intellectual property rights are to be regulated by specific federal patent legislation. The Federal patent law passed in 1996 covers pharmaceuticals and some agricultural products, specifically recognizing foreign patents. This law came in the midst of significant pressure from foreign companies who claimed that some Brazilian pharmaceutical companies produce medicine patented overseas without paying royalties to its creator.

Throughout Bill No. 306 traditional knowledge held by indigenous populations and traditional communities is recognized as a protected right of these populations. An entire section, comprising Articles 44–47 of the bill, addresses this issue. Additionally, Article 22 requires that holders of "possible intellectual property rights" be determined in the contract of access. Article 41 stipulates that "depositors of intellectual creations subject to protection by copyright, industrial property, crops, or any other mode of intellectual property" based on any genetic

resource or traditional knowledge must present a certificate of approval by the communities or populations of origin before requesting legal protection of the property. As mentioned above, the Wagner bill affords greater attention to indigenous rights in addition to those presented here. The GIARG bill does not specifically mention intellectual property rights but does recognize the special status of traditional knowledge.

PRIOR INFORMED CONSENT

Under the MoU, the prior informed consent of the source-country organization is required for transferring materials collected there to third parties as well as for publication of results. The MoU does not directly acknowledge the intellectual property rights of traditional healers or communities, but this could be further refined based on the internal agreements of the source-country institution.

It is clearly stated in several articles of the SP Bill that if access to traditional knowledge is involved, prior informed consent of these communities is required (Articles 1, 2, and especially 6, 8). Additionally, the SMA is instructed to stimulate prior informed consent of those communities outside of the Conservation Units (Article 8, Paragraph 2).

In the No. 306 and Wagner bills prior informed consent is required for any request of access to genetic resources or traditional knowledge. The GIARG bill does not address PIC at all, leaving much of the specific procedure for access up to further regulations and other legislation specific to the different parties to the contract.

Important differences between the Wagner and No. 306 bills regarding PIC are found in two articles. Article 45 of both states that local communities and indigenous populations have exclusive rights over their traditional knowledge and that prior informed consent of the community or population in question is required before any contract for access to this knowledge is granted. Bill No. 306 further states in the same article that prior informed consent must be obtained "according to clear and precise rules which shall be stipulated for this procedure by the competent authority." This clause is absent in the Wagner bill presumably leaving the protocol for PIC up to the community. The second difference is found in Article 46, where the Wagner bill stipulates that the traditional or local populations and indigenous communities themselves may deny access to the genetic resources existing in the area they occupy as well as to their traditional knowledge, whereas the same article in Bill No. 306 states that the local communities and indigenous populations may "request that the competent authority deny access to genetic resources in the areas they inhabit."

DISTRIBUTION OF BENEFITS

The NCI has used three different types of collaborative agreements in the past to gain access to genetic resources. Beginning in 1990, a Letter of Intent was signed between the source country and NCI through a collector, which acted as an agent for NCI. This type of agreement basically provided for consultations with the source country regarding royalties and publication, but the country did not actually participate equally in these decisions. Limited joint research and no technology transfer were mentioned. It was replaced in 1992 by the Letter of Collection, which

expanded the role of the source country in joint research and allowed it to negotiate directly with licensees. Nevertheless, the collecting was still performed by an associated (and generally foreign) collector, and only "sincere efforts" to achieve some transfer of technology were required from NCI.

The MoU is a new type of collaborative agreement developed by the Developmental Therapeutics Program of NCI. It was introduced in 1995, and is increasingly used as the model for partnerships between NCI and qualified organizations in source countries. The four main innovations introduced by the MoU approach are that: (1) all collection work is to be undertaken by the organization in the source country; (2) the source country can claim sole ownership of the invention if it isolated the compound; (3) source countries are to enter into negotiations directly with potential licensees (such as pharmaceutical companies); and (4) it requires source country authorization for any transfers of source country-originated material from NCI to third parties. Currently more than eleven NCI MoU agreements are in existence worldwide.¹¹⁰

The NCI must operate within the legal context that applies to Federal agencies of the US government. Some of the main restrictions resulting from this legal framework are that: (1) the agency may only act by statutory authority, and payments to its partners is strictly limited; (2) it is not permitted to engage in profit-making ventures; (3) it must give priority to US-based licensees if all of the bioprospecting work was funded by the agency; and (4) it can retain ownership over any intellectual property they create as a result of their research.¹¹¹

In spite of these limitations, the MoU has the most extensive and comprehensive benefit-sharing provisions of any NCI agreement and manages to circumvent some of the restrictions outlined above. The main benefit-sharing provisions of a MoU include:¹¹²

- monetary benefits are to be negotiated directly between the source country and the potential licensee of a patented product
- joint patent protection is sought for all inventions developed collaboratively
- facilities being available, the source country undertakes primary screening and later fractionation of compounds, with staff training and bioassay materials provided if these are non-existent
- results of NCI-based advanced screens must be repatriated within 90 days
- licensee is to resupply from the source country or provide monetary compensation
- distribution of material to third parties from the NCI is subject to prior informed consent from the source country
- publication must take place at a time agreed by source country organization and the NCI.

The MoU explicitly states that "it is understood that the development of a drug to the stage of marketing ... may require 10–15 years" (Clause 12). Since UNIP still lacks access authorization from the SMA, it has not started collecting in São Paulo, and to date the only benefits derived for UNIP consist of training of scientists. UNIP reportedly has samples that were collected in the past and in other states under the absence of access regulation. These samples could only be used by NCI if an export permit is obtained for them.¹¹³

The SP Bill establishes that state authorization for the commercial use of products or processes resulting from access will be formalized as a "Contract on the Use and Sharing of Benefits"

(Article 17). Some of the major elements that must be included in such a contract are the mechanisms by which equitable sharing of the benefits will be achieved, the pertinent intellectual property rights, and the sanctions and mechanisms available for solving conflicts among the parties. The parties to this contract must consist of: the state government, the owner of the land (public or private) or representative of traditional or indigenous community, the institution requesting access, and when applicable, the institution receiving the samples.

Articles 35 and 36 of the No. 306 and Wagner bills refer to benefit sharing as the "distribution of outcomes, whether economic or not, of research, development, commercialization or licensing derived from the access to genetic resources." In addition to payments and sharing of benefits, "a fair compensation [must be] ensured to the State, in the form of money or commercialization rights" and shall be used for conservation, research and inventory of genetic resources, and project support, as decided by the competent authority.

Benefits outlined in the GIARG bill are defined as royalties, technology transfer, licensing of products and processes, and human resource training. Here the distribution of benefits derived from the economic exploration of a product or process developed by either a national or foreign institution from samples under Federal jurisdiction must be distributed in a fair and equitable manner with the Union as agreed in further regulation.¹¹⁴ The same distribution of benefits is required for bioprospecting on indigenous lands; using indigenous or traditional knowledge; or on state, municipal, or private property, according to respective regulations.

COMPLIANCE MECHANISMS AND CONFLICT RESOLUTION

The MoU standard model does not contain any specific provisions regarding compliance or conflict resolution, except for Clause 16, which states that "no indemnification for any loss, damage or liability is intended or provided by any party under the MoU." Each party is liable for any such losses or damages resulting from the party's activities under the MoU.

Resolution 001-99 provides as a compliance incentive the interruption of research in the area if researchers refuse to sign the agreement or if the terms of the agreement are breached. The SP Bill designates the SMA together with the supervising national institution as those in charge of monitoring the access activities and ensuring that the terms of the agreement are followed. This bill also lists under Article 23 several sanctions for non-compliance including temporary or permanent confiscation of samples and equipment, fines, and patent suspension.

All three of the Federal bills place the onus of monitoring the process of request for access and access activities on the competent authority that will be named by the Executive Power. They also address possible violations to the law and consequent administrative and criminal sanctions.

CONSERVATION AND SUSTAINABLE USE

The MoU establishes that NCI wishes to "promote the conservation of biological diversity," and that it "recognizes the need to compensate source country organizations and peoples in the event of commercialization of a drug developed from an organism collected within their borders." Additionally, Clause 13 specifies that if the source country cannot provide the desired product to

a licensee in adequate quantity or price, the licensee is to pay the source country a negotiated amount that is to be spent in cultivation of endangered medicinal plant species. It could be argued that the extensive benefit-sharing provisions present in the MoU agreement, including recognition of IPRs and technology transfer, are likely to provide for better long-term opportunities towards sustainable exploitation of the resource in question.

Resolution 001-99 requires that researchers respect all Brazilian and international legislation dealing with research practices and IPR, as well the provisions of the CBD, and that they additionally contribute to divulgate the CBD goals within the scientific community, and population of the research area in particular.

Guaranteeing the sustainability of native genetic resources and the preservation of the environment are explicit goals of the SP Bill. The bioprospector will be solely responsible for any damage inflicted to the environment and the traditional communities (Article 16). It specifically authorizes the SMA to require an environmental impact assessment together with a given access request, and to deny access based on any of the following circumstances (Article 15):

- extinction risk of the species
- subspecies or varieties
- high rarity or endemism
- ecosystem vulnerability
- adverse effects on human health or the quality of life, or cultural identity, of the local or traditional communities
- risk of genetic erosion
- use of these resources to goals contrary to national interest and the treaties signed by Brazil.

All three Federal bills establish that the regulations are relevant to the conservation and sustainable use of the nation's genetic resources. The protocol for access requests outlined in Bill No. 306 requires applicants to provide information on the environmental sustainability of collection and the risks that may arise from access. The competent authority may also require the submission of an environmental impact study and report related to the activities being carried out. Article 13 of the No. 306 and Wagner bills call for the Government to "adopt measures to prevent serious and irreparable damage deriving from activities carried out under the terms of this Act," citing eight potential threats similar to those presented in the SP Bill. The article also states that scientific uncertainty should not be used as reason not to adopt necessary safety measures.

CONCLUSIONS

It is apparent from this case that the period during which a country is developing legislation is the hardest for interested parties, both national and international, to obtain access. Since Resolution 001-99 was adopted, the SMA of São Paulo is requiring ongoing field projects to negotiate mutually agreed terms within a short period. New access applications in São Paulo are on hold for the time being. This difficult situation may be made easier by the implementation of access laws, when guidelines for requesting access, regulatory competence among agencies, and the property rights of the resources should become clearer.¹¹⁵ For example, the Kew Royal

Botanical Garden in the UK has stopped bioprospecting activities in Brazil for fear that the uncertain legal situation would not guarantee rights in the case of a discovery. They are, however, pursuing activities in both Chile and Costa Rica where stipulations in access legislation are clear.¹¹⁶

The NCI MoU agreement seems to have remarkable flexibility given that it is proceeding in the midst of this confusing situation. It establishes extensive technology transfer and training in the first stages of the project, and these can be carried out during the time when the actual genetic resources are not yet accessible. In the case that no bioactive compounds are discovered, technology transfer and training may be the only substantial benefits to UNIP as a result of this agreement.

The situation in Brazil raises a number of questions about access regulation that have yet to be answered. First, how much legislation is necessary? Will a bill even be passed into law if it contains too many specific regulatory premises and directives, and, if so, what should the scope of it be? This question is highlighted by the very different nature of the GIARG bill versus the No. 306 and Wagner bills where the first is much more concise and leaves much of the specifics of regulation to be worked out later. Second, what will be the interaction between state and Federal law? Will applicants be required to file with both state and Federal agencies? Third, if the access permit process is too cumbersome for a given applicant, incentives for compliance may be low. In the regulatory process a balance must be reached between the control and flexibility goals presented by the CBD. Finally, will provisional access be granted during this period before new regulations are enacted, and will agreements negotiated and signed prior to new regulations be honored by state agencies?

Brazilian policy makers are working hard to establish regulations on access to genetic resources; however, they are confronted with many of the obstacles mentioned in Chapter II of this report. Some of the regulations being drafted are comprehensive and will require extensive participation by state agencies to process requests for access and monitor compliance to the terms of the agreements. Thus, adequate institutional capacity may be difficult to meet, particularly in times such as these, when budgets for state programs are being reduced. The constitutional amendment, if passed, should settle the issue of ownership over genetic resources. Although dissent may persist, many of the conflicts of interests among stakeholders could be minimized once the regulatory framework for access is put into place. Whether the new legislation will lessen the ethical and philosophical debates arising out of the special nature of genetic resources remains to be seen.

AN ATTEMPT TO BIOPROSPECT UNDER DECISION 391 IN COLOMBIA¹¹⁷

Andean Pact countries—Bolivia, Colombia, Ecuador, Peru, and Venezuela—may jointly harbor the largest proportion of the world's biological diversity, and some still possess a large proportion of their original forest cover. The perceived need to increase control over these vast genetic resources led to the formulation of Decision 391: a common regime on access to genetic resources in Andean Pact countries. Colombia, in particular, is a global conservation and research priority, accounting for 10% of the terrestrial species of plants and animals in the world

in only 0.77% of its surface area, while still retaining large tracts of undisturbed lowland forest.¹¹⁸ Hence, it is not surprising to encounter a recent prospecting request aiming to access Colombian genetic resources under the Andean Pact regime.

The attempt to establish an AGR agreement in Colombia was initiated by BioAndes—a private joint venture by Andes Pharmaceuticals, Inc. (Washington, DC) and ERS Asociados (Bogotá)—and was mediated by the Colombian Ministry of the Environment (MMA). The primary events discussed in detail below are summarized as follows:

- 1st BioAndes access application, February 1997
- MMA response, Resolution 1030, 14 November 1997
- BioAndes plea, November 1997
- MMA response, Resolution 0192, 25 February 1998
- 2nd BioAndes access application
- MMA response, Resolution 0984, 21 October 1998
- BioAndes plea, 6 November 1998
- Final MMA response, Resolution 1146, 9 December 1998

In February 1997 BioAndes submitted a formal AGR application for drug discovery in all Colombian territory. The request was modified in May 1997 to target the National Natural Park System (SPNN)—excluding park areas that are contested by civil law or inhabited by indigenous or Afro-American communities—thus limiting access to public property areas only. Access was denied by the MMA in Resolution 1030 of 14 November 1997. BioAndes then pleaded the decision, and the MMA responded confirming its original determination with Resolution 0192 of 25 February 1998.

In May 1998 BioAndes submitted a revised AGR application that excludes all natural parks whose territory is at all inhabited by traditional communities, limiting its activities to 10–15 selected areas. This application was also rejected in October 1998, after a protracted evaluation period. Again, BioAndes pleaded the decision and a final response from the MMA was presented in Resolution 1146 of 9 December 1998. All MMA Resolutions were grounded partially on Decision 391 of the Andean Pact, which institutes a common regime on access to genetic resources, thus establishing a first application of its aegis. Other regulatory frameworks considered in the Resolutions were the 1991 Constitution, Law 99 of 1993, and Law 165 of 1994 (the Colombian ratification of the CBD).

The application and decision-making processes were far lengthier and more involved than the sequence of events implies. Andes Pharmaceuticals, Inc. was founded in 1993 as a direct response to the CBD with the "mission to invert the current model for natural products drug discovery" by taking "state-of-the-art technology to countries rich in biological diversity." That goal was to be attained through a series of joint ventures in Bolivia, Colombia, and Venezuela, and direct participation would allow for collaborators to reap a greater portion of benefits from biologically active compounds.

Andes Pharmaceuticals' Colombian partner, ERS Asociados, is a private investment company dedicated to attract foreign know-how and headed by a former president of the Colombian National Institute for Industrial Advancement (IFI).¹¹⁹ BioAndes was founded as an equitable

(50/50) partnership between the two companies in 1994. In early 1996 BioAndes presented a letter of intent to the MMA declaring the aim of seeking access. BioAndes was then asked to wait until Decision 391 of the Andean Pact was formally implemented (2 July 1996). By the time the formal request was made, BioAndes had established collaboration with the Executive Secretary of the Andrés Bello Agreement (Cultural Office of the Andean Pact) for the botanical survey. Additionally, it had requested and obtained financial credit from the Council to the National Program for Technological, Industrial and Quality Development.¹²⁰ For its second application BioAndes established relations with Cenicafe (the scientific branch of the National Coffee Growers Federation) as a national support institution, and signed a letter of intent for collaboration with Biotec, the private biotechnology venture of Universidad del Valle (a Colombian university).¹²¹

In addition to the legislative criteria in the aforementioned regulatory frameworks, the first MMA decision considered texts presented by six civil advocates¹²² who demanded participation in the public process as stipulated by the 1991 Constitution, as well as a commissioned twofold (technical and judicial) evaluation. For technical examination of the first request, the MMA solicited the assistance of the National Biodiversity Institute (IVH), the Ad Hoc Biotechnology Committee (academic organization at *Universidad Nacional*, Bogotá), and at least one environmentalist NGO. A COLCIENCIAS (Colombian National Science Foundation) appraisal¹²³ of the first application—on which the Council based its credit approval—was considered, but used "*a título informativo*" or outside the scope of mandatory heed.

The main items of the analyses presented by the MMA in its first Resolution were:

- Geographic inaccuracy: the request aimed to sample sites within SPNN, without exact delimitation of coordinates for which access was requested.
- Taxonomic breadth: the request sought "access to all Colombian taxonomic groups, marine and terrestrial"
- Absence of strategic alliances with local partners for technology transfer
- Absence of explicit cash benefit-sharing schemes: the request made no mention of royalties but an "average annual donation" for conservation purposes
- The principle of equitable treatment: due to this principle, the MMA would henceforth have to concede future applicants "at least the same geographic and taxonomic realm, with the same breadth and scope."

Additionally, the MMA concurred with the civil advocates that BioAndes does not meet Decision 391's requirement of a "national support institution" because the supporting institution cannot be the same entity as the applicant. As logical consequences of these points, the MMA concluded that the application did not attend to the conservation and sustainable use of biodiversity or the fair and equitable sharing of benefits. It further sustained that ambiguous aspects of the request were open to interpretation, hence raising "doubts, uncertainty or confusion."

BioAndes pleaded this decision arguing that:

- The selection of natural parks corresponds to a geographic range necessary to warrant the viability of the enterprise.
- The taxonomic breadth is justified by the proposed bioassay method.

- There is no need for strategic or research alliances for the elaboration of extracts because it is a commonly used process.
- Decision 391 does not require a monetary compensation scheme as part of the application process.
- Since the resources accessed are renewable, their attraction for other applicants would not diminish for the same or different uses.

The MMA proceeded to confirm its original decision, elaborating on their original arguments and presenting new ones, e.g., the confusion between biological and genetic products in the application given that BioAndes "begins with the biological resource and ends with the genetic resource" in its assays.¹²⁴

The evaluation for the second MMA decision differs from the first as it emphasizes the following positive aspects of the second BioAndes application (1998):

- Increased success probability due to the bioassay process taking place within the country
- Collaboration with Colombian partners that would increase biological knowledge
- BioAndes accepts non-exclusivity as a condition for access
- Transfer of the screening technology, thus introducing new scientific and technological structure to the country and its know-how may be transferred to third parties, since there are no restrictions in the licensing agreement
- Training and capacity building
- Sharing of information stemming from research results with the Colombian scientific community.

Conversely, the main concerns of the MMA this time were:

- Taxonomic breadth (same as in the first decision)
- The application did not meet "minimum baseline offer from which to generate this [negotiation of cash benefit sharing] process"
- The bioassay technology could and would be used to screen for diseases different from cancer and that part of the research scope is unclear
- Lack of clarity regarding patents and IPR process, the objects subject to patent are not specified.

With regards to the advisory institutions, IVH abstained from assessment of the second request, as it was drafting its own access request. Two representatives of the People's Defense (*Defensoria del Pueblo*, a government body in charge of overseeing human rights and preventing their abuse) and two other individuals intervened under the participatory clause of the constitution, but made no comments on the application.

Other than reasons stemming from the above points, the MMA concluded that random sample collection for screening was contrary to the conservation of threatened species, subspecies, varieties, and races, and is also inconsistent with insect breeding, which is necessary to obtain significant reagent quantities for bioassay. All these grounds for denying access were stated in Resolution 0984 of 21 October 1998.

BioAndes pleaded this decision arguing that:

- Threatened taxa would be identified by means of drawings and photographs and thus avoided in the random sampling stage
- A consensus on the fairness and equitability of the monetary offer could only be reached through negotiation at the proper stage
- It is illogical to deny permit for cancer research because of lack of clarity with regard to research in other diseases
- It was clear from the application what the patentable products were.

Once more, in the subsequent Resolution the MMA confirmed its original decision point by point.

REGULATORY ENVIRONMENT

The legislative environment regarding biological resources in Colombia dates back at least to the Code of Renewable Resources passed in the 1970s, which conceded authority on access to certain genetic resources to the Institute of Natural Renewable Resources (INDERENA). The 1991 Constitution provides for the State's duty of preserving and planning sustainable use of the environment, as well as regulating entry, exit, and use of genetic resources. Law 99 of 1993 created the MMA and subsidiary research and administrative institutions, reaffirmed the "national patrimony" of biodiversity, and provided for protection of the "cultural, social and economic integrity of indigenous and black traditional communities" in the face of natural resource exploitation. Among the multiple obligations of the MMA, the following are relevant to the study of this case:

- "To formulate the national policy pertaining to the environment and natural renewable resources and establish environmental ordinance rules and criteria . . . so as to ensure the sustainable use of resources and the environment
- To reserve, delimit, and subsume areas that compose the National Natural Park System and national forest reserves, and rule their use and administration
- To regulate, according to law, the collection, use, management, research, import, export, distribution, and trade of species and genetic lineages of wild flora and fauna; regulate the import, export, and trade of such genetic material, establish control and overseeing mechanisms and procedures, and propose the regulations needed to claim payment or recognition of rights or royalties in favor of the Nation derived from the use of genetic material
- To settle the global allowances and determine species for use from natural forests and the collection of specimens from wild flora and fauna, considering the offer and renovation capacity of such resources . . ."

Colombia ratified the CBD at the national level in Law 165 of 1994.

Decision 391 of the Andean Pact is pivotal in this case because it provided the framework for the MMA's evaluation. Among other goals, Decision 391 aims to ensure fair participation and equitable sharing of benefits derived from access and provide the basis for the recognition and valuation of genetic resources in their tangible and intangible forms, especially in relation to indigenous, Afro-American, and local communities.

Decision 391 (Article 6.1, see also Article 5 and 6.2.) reconfirms state sovereignty and grants ownership of genetic resources and derivatives to the member nation or state, while acknowledging the rights of indigenous, Afro-American, and local communities over their knowledge, innovations, and practices associated with genetic resources and derivatives. Furthermore, it arranges for a transitory disposition to "establish a special regime or a harmonizing norm . . . directed towards strengthening the protection of the knowledge, innovations, and traditional practices of indigenous, Afro-American, and traditional communities . . ." The term for submitting this overarching legislative proposal, however, was postponed subsequently.

Decision 391 also provides an AGR blueprint that has been analyzed elsewhere.¹²⁵ In proposing guidelines for contracts, however, it leaves the specifics of benefit sharing, technology transfer, capacity building, and traditional knowledge open to case by case negotiation, while aspiring to accomplish benefit equitability goals for all involved.

STAKEHOLDERS

Decision 391 only nominates the State and applicant as parties in the access contract, although it does mention other stakeholders in its "Definitions" preamble. The Colombian State was represented by the MMA, which made the final decision to deny access, and the applicant was BioAndes. There were, however, interventions by individuals during the application evaluation and decision process. Such interventions are warranted under the principle of participation consigned in the 1991 Constitution and Law 99 of 1993.

These individuals (some of whom are part of *Grupo Semillas*) initially propounded that under the precautionary principle consigned in Decision 391, the MMA could abstain from making a decision until legislation was fully in place and internal regulations had been installed. They further contended that the "national support institution" requirement in the Decision 391 application primer had not been fulfilled because the identified national institution was BioAndes itself, and that there was no technology transfer because it involved "procedures that already take place in the country . . . such as biological material collection."

The MMA contended that the precautionary principle was not applicable because there was no imminent threat to biodiversity resulting from the access request, agreed with the interpretation of "national support institution", and pointed to a confidential part of the technical assessment with regards to the third observation.

In March 1998, *Grupo Semillas* released a communiqué of the implications of the request and decision for indigenous, black, and peasant groups. The NGO highlighted that:

- BioAndes did not overtly consider intangible knowledge as an essential part of the bioprospecting scheme, yet it intended to "examine plants with known medicinal activity . . . purchased at market places."
- BioAndes planned to use "popular literature" that, according to the NGO, "should not be appropriated by a private company for its individual profit."
- The company would collaborate with Colombian botanical gardens and herbaria, which encompass previously collected ethnobotanical information.

- Many parks within the SPNN include indigenous, black, and peasant communities, which were not considered as stakeholders or sources of traditional knowledge.

Furthermore, they argued that the legal regime of the SPNN was incompatible with "commercial goals or patenting by private individuals or entities, because such goals give the [research] activity an economic connotation" as opposed to "research, that should be performed in general interest." These considerations were not part of the MMA decision, but are illustrative of the view that this advocacy group had of the request.

There were no specific interventions by concerned stakeholders in the second MMA decision. Since the application was rejected, none of the possible stakeholders mentioned in Decision 391 became active in subsequent stages, e.g., negotiation.

PROPERTY RIGHTS

Tangible property

The Colombian Hall of Consultation and Civil Service of the State Council determined in August 1997 that "genetic resources are goods of public domain and belong to the Nation, as they are part of the natural resources or riches." Furthermore, the land corresponding to the SPNN that BioAndes intended to bioprospect formally belongs to the State in its entirety (i.e., not only its natural resources).¹²⁶

However, as in other park systems in developing countries, parks in the SPNN are sometimes mere boundaries drawn on a map where colonizer, peasant, indigenous, and black communities settle and often practice all sorts of economic activities. They effectively hold tenure of the land and physical resources therein, although the Colombian Agrarian Reform Institute may not concede property deeds for those areas. In some cases, there are actual titles extending property rights to areas within a park because the protected jurisdiction was created recently and without consultation.¹²⁷

Both BioAndes applications stressed the desire to access areas that were undisputed State-owned property. BioAndes would also refrain from accessing areas determined by the Colombian government to be problematic in terms of security. In the latter case, it would strive to "identify alternative access areas." This last stipulation is relevant insofar as many of the protected areas include zones disputed by armed groups.¹²⁸

Intellectual property

The distinction between tangible and intangible components of genetic resources in Decision 391 is explicit, although there is no actual regulation of the details of intellectual property rights. Traditional knowledge and communities are mentioned, but the latter are not instated as parties to access contracts. When the request was evaluated, this, like all aspects of access legislation, remained unregulated in Colombia and there is no mention of traditional knowledge as being problematic in either MMA decision.¹²⁹

BioAndes did not apply for access to associated indigenous knowledge, purporting to use a "licensed bioassay technology [that] does not require information regarding the natural product (e.g., indigenous knowledge), and is designed to bioassay any natural product (e.g., plants,

microbes, fungi, etc.) without regard for the information therein." Nevertheless, the application also stated that if BioAndes were to use indigenous knowledge it would only do so under strict criteria of "informed consent, mutually agreed terms, and recognition of intangible property related to genetic resources." According to *Grupo Semilla*, the application also stated that BioAndes would use published literature (particularly the series on "Promising Plant Species" by the Andrés Bello agreement) and evaluate common remedies purchased in marketplaces.

In terms of products derived from bioprospecting, BioAndes would "generate its revenue from granting licenses and selling new bioactive compounds to the pharmaceutical and biotechnology industry in collaboration with its commercial partner, Andes Pharmaceuticals". In this respect, it would follow ordinary patent and licensing agreements under Colombian law. Nonetheless, obscurity regarding the participation of the State in benefits deriving from IPRs and the patenting processes was one salient negative aspect reported in the second MMA decision. BioAndes clarified that "participation of the State in the economic aspects [deriving from patents] of the project would take place through the reception of monetary and non-monetary benefits agreed upon through the access contract." The final word from the MMA raises two related concerns regarding (1) the proprietary rights that BioAndes would have on all extracts and (2) the possibility of testing extracts useless in cancer for activity against other human and agricultural diseases.

PRIOR INFORMED CONSENT

Since no agreement was finalized between the parties, there can be little elaboration on the details of interaction between provider and user. It may suffice to say that formal applications were the way in which BioAndes sought to obtain prior informed consent.

DISTRIBUTION OF BENEFITS

The cash benefit offers of both applications were criticized and named as one of the reasons for rejecting the applications. Decision 391's access application primer includes no requirement of monetary benefit arrangements, and BioAndes interpreted this to mean that economic benefits were to be defined and discussed in the negotiation phase. Indeed, no specifications of cash benefits—up-front payments, royalties, or access fees—were solicited by the MMA in more than 30 information requests to BioAndes between February and November 1997. Nevertheless, the distribution of (monetary) benefits aspect of the first request was interpreted by the MMA as "not pursuant of these [Constitutional, CBD, Decision 391] principles, for fair and equitable sharing of benefits for the State derived from access is not set forth."

In its "Monetary Benefits" section, the first application stipulates a US \$2.5 million investment in the local economy, of which US \$300–400,000 would be directly transferred to Colombian institutions, botanists, technicians, and other experts involved in the project. Additionally, an undetermined percentage of annual collection budget and 50% of the net income derived from commercialization of natural products that BioAndes would receive from Andes Pharmaceuticals would be transferred to national institutions (to be designated by the MMA).

The second BioAndes application included a detailed monetary benefit-sharing scheme, as follows:

- 5% of collection budget to collaborating local herbaria (US \$50,000 in the first three years)
- An unspecified (confidential) percentage of annual gross income as royalty payment
- 50% of income from sale of final BioAndes products in the Colombian market
- 35% of annual gross income as income tax
- 3% of annual gross income as industry, commerce and property tax.

BioAndes would also deposit 50% of all voucher specimens per species at an approximate cost of US \$455,000 in the first three years, and requested that this be considered as part of access payment. These monetary benefits would accrue from 50% of the net income from commercialization of patents, licenses and compounds that Andes Pharmaceuticals would transfer to BioAndes.

Non-monetary benefits included in both applications were:

- Technology transfer: Andes Pharmaceuticals' proprietary screening technology would be licensed to BioAndes, a Colombian company, thus adding value to Colombian natural products
- Training of Colombian scientists and technicians in procedures unavailable in any other facility
- Joint research with Cenicafe on a coffee pest
- Infrastructure and institutional capacity building by employing at least 18 professionals in biology, chemistry and botany
- Shared information of research and development results with the MMA and;
- Contributions to the National Inventory of Colombia through voucher specimens deposited in collaborating herbaria.

In its second decision, the MMA praised the non-monetary benefits but determined that "although the monetary component is an object of negotiation, the request does not fulfill a minimum base from which this [negotiation] process can be generated." In their response to the second BioAndes plea the MMA further elaborated that "there is no balance between the State's contribution and the applicant's offer as economic compensation . . . [given that each case should be separately analyzed] it is irrelevant that the BioAndes economic proposal had been based on international standards." Nonetheless, no indication is given in any of the Resolutions as to what monetary offer would be sufficient for the MMA to consider as baseline for negotiation.

According to Edgar Asebey (CEO of Andes Pharmaceuticals, Inc.), the main benefit from the BioAndes applications consisted of the technology transfer and in-country capacity building that would derive from the operations. By licensing high-throughput screening methods to be used in Colombia, BioAndes would increase the value-adding portion of the drug discovery process. On the other hand, the financial risks of drug discovery would also be shared with Colombian financial partners. He contends that the MMA decisions stem from scientific advisors that were unfamiliar both with this particular bioassay method and the regular procedures involving state-of-the-art technology licensing. Furthermore, he says that since 24,000 people die of cancer in Colombia each year and the necessary drugs to treat them are imported, progress in the screening process would eventually have a positive social impact on the Colombian health system.

COMPLIANCE

The first BioAndes application pledged to abide by all the regulatory frameworks operating in Colombia (see Regulatory environment, above). The second application contained an evaluation scheme consisting of inspection and monitoring of facilities and operations by the MMA every 3–6 months, an activity report to the MMA every 3–6 months and the hiring of an external financial auditing firm by BioAndes.

This latter application stipulated that BioAndes would:

- Obey present and future biosafety laws and would not use genetic engineering
- Not use intangible knowledge or be involved in activities that might have adverse effects on cultural identity
- Not export Colombian biological resources, as the collected organisms would be researched in the country
- Not collect threatened species.

One of the main concerns expressed by the MMA was the problem of enforcement, given the broad taxonomic and geographic scope of the requests. Thanks to this experience, the MMA has reportedly refined its criteria for requests and currently requires that "any access request must specify the resource, including the taxonomic group to which it belongs, to facilitate monitoring and in order to determine the scope of the request."¹³⁰ The MMA is currently drafting pertinent regulations to be submitted to Congress¹³¹ while internal ones were already instated by Resolution 620, 7 July 1997.

The Minister of the Environment acknowledged the institutional capacity limitations of MMA. According to him: "realistically in this century we are not prepared for a transaction of this magnitude . . . what we are talking about with BioAndes is science and technology of the 21st century . . . therefore there are still some difficulties in delving with them into negotiation."¹³² Another MMA official noted that the protracted evaluation (and possibly the rejection) of the application was related to the lack of consensus and numerous doubts that the staff had, the lack of infrastructure, and the novelty of the subject as a whole.

In the eyes of BioAndes, however, the process itself does not encourage compliance, since the costly application (Edgar Asebey claims that Andes Pharmaceutical incurred US \$1 million in transaction costs while trying to obtain access to Colombian biodiversity) may not be met with fair consideration, but rather one "informed by radical advocacy groups, subject to the vagaries of changes in administration, and tainted by an exaggerated appreciation of political correctness." Andes Pharmaceuticals is no longer operating in Andean Pact countries. At the national level, there have been only two more access requests (both by scientists). One by a Colombian researcher working in Germany who quit after realizing the ramifications of the application process, and one by a local researcher undertaking a project in a natural park. The latter has not been resolved. The application process stipulated in Decision 391 applies to all instances of access to genetic resources, by foreign, national (including State agencies and representatives), commercial, or non-commercial parties.

SUSTAINABLE USE AND CONSERVATION

One of the main lines of argument by the MMA was that because the species to be collected were not specified beforehand, the random collection method proposed by BioAndes would not guarantee the conservation and sustainable use of threatened species. In the first plea BioAndes emphasized that the MMA would be thoroughly informed of the species sampled by establishing control mechanisms that would void the contract if the company did not fulfill its obligation of not collecting threatened species. In the second plea BioAndes referenced a method to avoid collection of threatened species by identifying organisms in the field with the aid of photographs and drawings.

BioAndes' pleas notwithstanding, the MMA concluded that the impact on wild populations of collected and uncollected species and on the balance of the natural system was still unacceptable. The MMA also noted that threatened species lists, such as those that the IVH or CITES could provide, were inadequate due to the "state of development of the subject and species inclusion criteria." As a final caveat the MMA pointed out that a species that is not threatened as a whole may have "particular populations presenting a critical state."

The possible larger effects on development and conservation can only be speculated on, since there was no contract. Given the conditions of the SPNN and the MMA, sources of revenue (contractual or otherwise) are badly needed. Indeed the new administration (instated in August 1998) had resolved to downgrade the budget of the MMA back to the size it was when environmental agencies were part of the Ministry of Agriculture (as they were prior to Law 99 of 1993). In an impromptu response to bolster its importance in the national landscape, the MMA staged an international conference about Colombian biodiversity in Washington, DC in October 1998.¹³³ National budget allocation, however, is at a prime since 1998 was the year of least economic growth for Colombia in history.¹³⁴ Nonetheless, there is no way of knowing whether the outcome of this particular bioprospecting scheme would have resulted in benefits—financial or otherwise—to the parties or ecosystems involved.

CONCLUSION

The Colombian Ministry of the Environment purportedly utilized the regulatory framework of Decision 391 to evaluate and reject the BioAndes AGR applications—the first in any Andean Pact country. The MMA followed the proprietary rights and the overall application process prescribed by the Decision, but the specific reasons invoked by the MMA in its Resolutions are not clearly linked to Decision 391. The MMA's emphasis on monetary benefits is spurious because Decision 391 does not require that applications stipulate monetary benefits. On a technical note, the principle of equitable treatment in the first MMA decision pertains the non-discrimination of all applicants in terms of application process, but it does not mean that all future applicants would have to be granted the same degree of access.¹³⁵

At a more general level, the Decision 391 requirement of a "national support person or institution," given that the application process should be equally required of all users, deserves careful attention. Are national institutions obligated to name another national institution or person as their national support? How about local scientists or students? These, and other

questions regarding the scientific and legal soundness of both the applications and their rejections remain open.¹³⁶

AN INTERNATIONAL COOPERATIVE BIOPROSPECTING EFFORT AND THE EVOLUTION OF LEGISLATION IN CAMEROON¹³⁷

The dynamic history of AGR legislation in Cameroon has been tied to the development of several access agreements involving pharmaceutically and phytomedically valuable plant species. The case of *Ancistrocladus korupensis* paved the way for the negotiation and subsequent formation of a national policy framework for research agreements and benefit sharing for local communities. Activity surrounding collection of *Prunus africana* further defined the ways in which access to Cameroon's wealth of non-timber forest products is regulated, as well as how such agreements are designed to support the aims of conservation and sustainable use.

Currently, access to Cameroon's biodiversity-rich forests and the support of benefit-sharing arrangements through research has been achieved most successfully through the practical implementation of the African International Cooperative Biodiversity Groups (ICBG). The focus of this US government-sponsored initiative is establishing "an integrated program for the discovery of biologically active plants for drug development and biodiversity conservation [while] at the same time ensuring that local communities and source countries derive maximum benefits for their biological resources and their intellectual contribution."¹³⁸

The African ICBG is unique in that it is the largest cooperative of its type, surpassing ICBG programs in other regions. This consortium of collaborating scientists from more than sixteen institutions in the US, Cameroon, and Nigeria is currently recognized as an important expansion of existing efforts to identify plants useful for drug development and tropical disease treatment.

REGULATORY ENVIRONMENT

A 1985 agreement involving the National Cancer Institute (NCI) and the Missouri Botanical Garden (MBG) in conjunction with the Center for the Study of Medicinal Plants in Yaounde allowed for collection of one 0.5 kg sample of dried stems and leaves of *Ancistrocladus korupensis* to be used for the research and development of bioactive compounds by NCI. The species was identified as a potentially useful medicinal plant in 1987. Extracts of *A. korupensis* were found to exhibit significant *in vitro* activity during a screening for anti-HIV characteristics. A subsequent bioassay-guided fractionation of the extract produced michellamine B, which, due to its biological activity, provided NCI with hope that a valuable medicine could be developed from the leaves of this forest liana.¹³⁹ Original collections of this species took place within the boundaries of Korup National Park.

In 1992, an agreement between NCI and the MBG and the University of Yaounde's Center for Health Sciences was forged which would step up the process of collection, research, and cultivation; a Letter of Collection served as the first formal contract between these parties. But the absence of a national legal framework to guide the process of collection resulted in confusion once the plant yielded a useful compound. The Government of Cameroon did not acknowledge

the agreement, on the grounds that the University did not have the authority to represent the country's interests. An Inter-Ministerial Committee to address the issues of access to genetic resources and benefit sharing related to *A. korupensis* was formed in 1993, and the Prime Minister's Follow-Up Commission for the Exploitation and Conservation of *A. korupensis* was established in 1994. This resulted in the enactment of new legislation and led to national regulation of access to genetic resources.

Forestry Law No. 94/01 of 1994 proclaimed national sovereignty over natural resources, included some provisions for access and benefit sharing, as well as prior informed consent, and assigned regulatory authority to the Ministry of Environment and Forestry, the Ministry of Scientific and Technical Research, and other relevant ministries.¹⁴⁰ The Framework Law on Environmental Management No. 96/12 of 1996 includes additional language on access and benefit sharing and defines national policy, focusing on the need for scientific research and for accordance with the CBD in matters of access to genetic resources. Article 65 (1) of this law states that the exploration and exploitation of genetic resources should be carried out under the conditions of the CBD, and in collaboration with relevant institutions and communities within Cameroon.

The emergence of the ICBG has allowed the process of access to genetic resources to be played out increasingly through universities and research institutions within the Cameroon and Nigeria region, increasing their access to funding and resources. In this way, highly developed systems of local traditional knowledge that in the past suffered from a lack of institutional support have been able to achieve new levels of representation. The structure of the ICBG and the benefit-sharing arrangements it is designed to deliver have shifted in emphasis from regulation by government ministries to collaboration that is generated at the community level. The written agreement now used by the ICBG effectively provides a model for the establishment of an access and benefit-sharing system, for which framework legislation exists in both Cameroon and Nigeria.

STAKEHOLDERS

All those organizations, institutions and individuals that have been involved in the collection, use and research of *Ancistrocladus korupensis* as well as their regulation can be considered stakeholders. The actors involved in the *A. korupensis* case include:

- Approximately 100 villages in the Korup province of southwest Cameroon, comprising a combination of indigenous tribes hailing from two main ethnic groups, the Bantoid Ekoi and the Cameroon-Congo Bantu. Local communities include the Ejagham tribes, Ibibio tribes, and Korup people (Bantoid), as well as Oroko and Mbo tribes (Bantu).
- The Government of Cameroon. The Ministry of Environment and Forestry, Ministry of Scientific and Technical Research, and the Prime Minister's Follow Up Commission for the Exploitation and Conservation of *A. korupensis* are the three government bodies primarily responsible for regulating biodiversity prospecting. In the process of legislation development, however, the Ministries of Industrial and Commercial Development, Health, Higher Education, Justice, Finance, and the Prime Minister's office have also played roles.

- The National Cancer Institute. This US agency began collecting in the Korup area in 1985 under a world-wide tropical plant collection program, which then led to an initiative focused on the discovery and development of drugs used to treat AIDS.
- The Missouri Botanical Garden, which was contracted by NCI to conduct commercial collections.
- The University of Yaounde. Along with the NCI and the MBG, this university was involved in initial collections of *A. korupensis*, as well as investigations of the plant's cultivation and distribution within the Korup area. The university's Center for Health Sciences signed the NCI Letter of Collection in 1992, although the Government of Cameroon would later revoke the agreement.
- Purdue University was given a three-year contract in 1993 to assist NCI, MBG, and the University of Yaounde in researching the propagation and cultivation of *A. korupensis*.
- The Korup National Park, established by the Government of Cameroon in 1986, includes the Korup Project, a WWF-sponsored effort to conserve biodiversity within the forest and surrounding communities. Because *A. korupensis* was collected from the Korup Project area, the participation of communities within the Park boundaries and the efforts of WWF and others involved in the Project have collectively represented the area in this case during negotiations regarding the NCI Letter of Intent that was declared illegitimate by the state. The Korup Project is considered a stakeholder in that the Project itself stands to benefit from the research and development efforts undertaken within its borders.

The African ICBG agreement includes the following parties:

- The Bioresources Development and Conservation Program (BCDP), an "international umbrella organization" acting as "primary administrator, monitor, and arbiter of the various interests involved" in the African ICBG, with established autonomous branches in Cameroon and Nigeria.
- Community organizations: Traditional Healers Associations, Nigerian Union of Medical Herbal Practitioners, and other local communities.
- Government organizations: US National Institutes of Health, National Science Foundation, USAID, Walter Reed Army Institute of Research, Smithsonian Tropical Research Institute, Ministries of the Governments of Cameroon and Nigeria, and the Enugu Regional Herbarium.
- NGOs: WWF, IUCN, Nigerian Conservation Foundation, and other local NGOs.
- Academic Institutions: University of Dschang (Cameroon), University of Ibadan (Nigeria), and the International Centre for Ethnomedicine and Drug Development (Nigeria).

PROPERTY RIGHTS

Tangible property

The Korup Forest Reserve was designated in 1937 and served as a border between pre-colonial societies, a "boundary wilderness" over which no single authority could exert control. Land tenure and forest management are now determined on a village basis according to traditional laws, with no central organizational structure. All the land in the Korup area has been appropriated by the local inhabitants, with current boundaries commonly defined between villages and particularly between ethnic groups.

Part III of Forestry Law No. 94/01 divides forests into permanent and non-permanent types. Permanent forests include state and council forests, while non-permanent forests include communal forests, community forests, and privately owned forests. Management guidelines for individuals and local communities differ among these different types of forest, and are specified in different sections of the law. These guidelines adhere to the rights of the local people to "harvest all forest, wildlife and fisheries products freely for their personal use, except the protected species."

Section 11 of Law 94/01 establishes national sovereignty over all genetic and biological resources, and requires prior informed consent from the Government for any scientific, commercial, or cultural exploitation. Tenure over plant genetic resources is addressed in Sections 9(2) and 39(4), where certain medicinal plants and products of "particular interest" are proclaimed to be "special," in that even those found on individual private property are subject to approval by the appropriate government ministry before they are exploited in any way.

Section 17(2) goes on to establish that "customary communities and members thereof as well as any person of Cameroonian nationality occupying or exploiting national lands by August 5, 1974, shall continue to do so and may apply for certificates of title over these lands." This means that while the rights of indigenous people have been somewhat respected, restrictions on the use of their lands have been created by the Forestry Law, superseding customary law dealing with land tenure. Although Law 94/01 allows for private ownership, the trees and all other forest resources growing on the land have been effectively nationalized, meaning that even if land were legally owned by an individual, all naturally occurring trees are property of the State.¹⁴¹

Intangible property

Neither one of the two laws discussed above provides a basis with which to regulate intellectual property rights. Under the ICBG, a large emphasis is placed on traditional knowledge and local healers associations, which are well represented in the region. Collaboration with the Nigerian Union of Medical Herbal Practitioners and local communities in Nigeria and Cameroon include consultation with herbalists and healers in identification, research, and development. Payment of royalties to contributors of local knowledge has been implemented through trust funds.

The ICBG's Cooperative Research and Development Agreement (CRADA) represents the understanding shared by all members of the Cooperative, and deals with intellectual property rights (licensing, royalty sharing, trademark, copyright, copyright and trade secrets), prior informed consent, and other benefit-sharing arrangements. Negotiations under this agreement are entrusted to the Walter Reed Army Institute of Research in the US, and supposedly safeguard African scientists from pharmaceutical companies known to violate such agreements.

PRIOR INFORMED CONSENT

Prior informed consent is required under the Forestry Law as explained above; one must obtain consent of the Ministry of Environment and Forestry and the Ministry of Scientific and Technical Research, as well as a local community or collaborating organization. However, no measures were taken to implement this provision until recently. A lack of coordination between

the relevant ministries and a lack of clarification regarding the respective responsibilities emerged during the *A. korupensis* case and the NCI Letter of Collection.

DISTRIBUTION OF BENEFITS

Benefits under the NCI Letter of Collection included: (1) the provision of test results, equipment, infrastructure support, and technologies; (2) research exchanges; (3) payment of royalties to the state; and (4) the promise to seek the host country as the first source of raw materials found to be commercially valuable. Benefits for local communities resulting from the collaborative research and development process undertaken by NCI and the University of Yaounde involved training in nursery and agronomic techniques, and the development of alternative income generating schemes through supply of raw materials.

The hope of financial benefits in the form of royalties inspired the Government to become progressively more involved in the *A. korupensis* case, culminating in the enactment of the 1994 Forestry Law, that grants it the right to control the distribution of royalties. Section 11(2) states: "The economic and financial spin-off resulting from their use shall be subject to the payment to the State of royalties the rate and conditions of which shall be laid down, to the prorata of their value, by an order of the minister in charge of finance upon the proposal of the competent ministers." The text of the law, however, does not clearly define a central authority to oversee and regulate access and benefit-sharing issues. As a result, despite the establishment of a legal framework, no institutional support was effectively enacted to carry out the benefit-sharing provisions.

The ICBG describes two types of benefits under the CRADA agreement. "Process" benefits result from the research and development phase of the project: technology transfer, infrastructure and equipment, training, grants to local associations, workshops, and collection fees. "Long-term" benefits result from the commercial product phase of the project, and are mainly financial: royalties, protection of trade secrets, sourcing, and trust funds. This includes an International Trust Fund and two independent Trust Funds in Cameroon and Nigeria set up to disburse revenues of up to 50% of royalties to contributors of local knowledge and communities.

The major obstacle to accomplish the extensive benefit-sharing provisions outlined by the ICBG is the lack of coordination among the parties, particularly regarding the implementation of legal frameworks for access in both Cameroon and Nigeria. An inter-ministerial or inter-agency body to provide a focal point for benefit sharing is now being called for in Nigeria as the policy process develops. As regulatory mechanisms are put into place, the scientific and technological strengths of the ICBG Program will need to be supported in both countries through increased national capacity and collaboration among institutions, both public and private.

COMPLIANCE AND CONFLICT RESOLUTION

The Ministries of Environment and Forestry, Scientific Research, Finance, and Housing and Town Planning all have a role in implementing the Forestry Law and the Framework Law on Environmental Management. The difficulty with the provisions outlining these ministries' respective duties is that they are primarily still on paper, that is, the institutional capacity needed

to carry out the enforcement is not yet in place. It is then difficult to ensure that what appears on paper will be effectively realized, and it is impossible at this time to evaluate how successful these provisions will be when the ministries in fact construct and maintain the necessary means to allay conflict and monitor compliance.

CONSERVATION AND SUSTAINABLE USE

The WWF-sponsored Korup Project addresses conservation of biodiversity in Korup National Park through forest management, education, research coordination, and rural development. The Project received support and some infrastructure development from the activities dealing with *A. korupensis* collection and research. Sustainable collection of *A. korupensis* leaf litter (rather than live leaf material) began in 1993 and has proven successful.

The recent discovery of *A. korupensis* in the forests on both Cameroon and Nigeria has raised the issue of regional cooperation in the implementation of access and benefit-sharing measures. Conservation of biodiversity is one of the ICGB's goals, and includes provisions for *in situ* research programs and training, inventory of species, and support for extractive reserves which are provided by numerous institutions such as the Smithsonian Institution and WWF.

It is hoped that in this case, as elsewhere, benefits derived from the commercial use of genetic resources at the national and local levels will create economic incentives for the preservation of biodiversity. The efforts of the African ICGB could conceivably lead to an efficient sustainable approach to conservation, as the 3.2 million square kilometers of closed and open broad-leaf forests in West Africa—the second largest contiguous expanse of moist tropical forest in the world—are treated increasingly as a whole system rather than as isolated fragments broken by artificial lines.

CONCLUSION

The case of access regulation in Cameroon provides an example of the process by which national legislation may be enacted based upon what began as one instance of bioprospecting—the collection of *A. korupensis* in 1987. The resulting access framework in Cameroon has attempted to address several of the obstacles outlined in Chapter II, including those arising out of the special character of genetic resources and the conflicts between ownership and tenure. Along with Nigeria, Cameroon is still struggling to overcome the dearth of legal, institutional and scientific capacity that impairs its attempts to regulate access and implement successful benefit-sharing mechanisms. Nevertheless, under the umbrella of the African ICBG and through the participation of more than sixteen institutions in various aspects of the project, both countries stand to gain much in the way of shared information and resources. Although the ICBG includes a detailed benefit-sharing plan, the success of this regional effort rests upon the relative strengths of collaborating parties, specifically the various government ministries and agencies, which have the task of providing a clear and reliable policy framework for commercial partnerships and national and regional bioprospecting agreements.

THE UNIVERSITY OF THE SOUTH PACIFIC–STRATHCLYDE INSTITUTE OF DRUG RESEARCH BIOPROSPECTING AGREEMENT IN FIJI¹⁴²

In May 1997 an agreement was signed between the University of the South Pacific (USP) in Suva, Fiji, and the Strathclyde Institute of Drug Research (SIDR) of the University of Strathclyde in Glasgow, Scotland, to undertake a bioprospecting project in the *tikina*, or county, of Verata, Fiji. Initiated by USP as part of a larger project entitled "Natural Product Development and Conservation in Fiji" (NPDC) funded by the Washington, DC-based Biodiversity Conservation Network, the purpose of the bioprospecting agreement was to create financial and non-financial benefits to biodiversity preservation at the community level. The brainchild of Dr. William Aalbersberg, USP professor of natural products chemistry, the agreement also constituted a targeted effort to interpret and apply the mandates of the CBD and best practices as laid forth in Costa Rica and elsewhere vis-à-vis access to genetic resources and distribution of benefits generated therefrom.

A second agreement formed between USP and the *tikina* of Verata (USP–Verata contract) constituted a progressive effort to ensure that the benefits of the bioprospecting endeavor be distributed equitably at the community level. The bioprospecting contract provides for the sampling of 500 marine and terrestrial organisms in the fishing grounds and forests of the *tikina* of Verata.

REGULATORY ENVIRONMENT

Prior to the USP–SIDR contract and the NPDC project, regulation of access to genetic resources was non-existent. Through proactive consultation with various government institutions, including the Department of Environment (DoE), created specifically to address the implementation of the CBD and Agenda 21, the bioprospecting agreement served to highlight the most important aspects of access regulation and greatly assisted in the formation of article 249 of the national Sustainable Development Bill, which concerns access to genetic resources.

STAKEHOLDERS

While the USP–SIDR contract explicitly recognizes only the contracting parties (USP and SIDR) as stakeholders in the bioprospecting project, implicit inclusion of other stakeholders is made in several ways. First, reference is made to the government of Fiji and the "resource owners." Statement (h) of the contract preamble states: "USP will obtain all required permissions from the Government of Fiji, and the prior informed consent of the resource owners, to extract biological samples and export them from the country." Statement (i), meanwhile, identifies as stakeholders the people of Fiji as well as the natural environment: "One of the purposes of the agreement is to promote the conservation of biodiversity in Fiji by creating incentives for species conservation and to provide an equitable share of profits to the people of Fiji. In collecting extracts, cultural and ecological values will be respected."

The USP–Verata contract explicitly recognizes the *tikina* of Verata, the Biodiversity Conservation Network, and specifically, the USP School of Applied Sciences as stakeholders in the USP–SIDR bioprospecting project. As the primary signatory of the bioprospecting

agreement, USP therefore has officially broadened the field of stakeholders in a binding legal agreement.

In forming the bioprospecting agreement, the NPDC project expanded the field of stakeholders to include the Rainforest Alliance's Natural Resources and Rights Program (then headed by Charles Zerner) whose interest is to promote the equitable distribution of benefits arising from natural resource exploitation around the world. In addition, an advisory group of bioprospecting experts, including Sarah Laird, Bronwyn Parry, and Michael Gollin, reviewed and critiqued the agreements prior to their enactment.

Finally, a regional native-rights group which had called for a general ban on bioprospecting in the South Pacific was included as part of a regional "reference-group."

PROPERTY RIGHTS

Tangible property

In Fiji, 83% of the land is communally owned by indigenous Fijians as a result of the codification of a pre-colonial system of customary land tenure. The *tikina* of Verata is therefore the legal owner of the land and resources contained thereon. Decisions regarding its use are made at the level of the community council by unanimous consensus.

Ownership of marine areas, including traditional fishing grounds, is governed by both national and customary law. The Native Lands and Fisheries Commission places ownership of fishing grounds at the level of the local community. The 1990 constitution recognizes indigenous rights over all resources located in fishing grounds, including the seabed; however, the state maintains the right to collect unspecified royalties on resources extracted from the seabed. The NPDC project has strengthened local ownership of fishing grounds, which has had the effect of limiting access to outside fishers who may have been dependent on previous unregulated access for their livelihoods.

Intellectual property

The issue of intellectual property rights attached to ethnobiological knowledge is notably absent from both the USP–SIDR and USP–Verata contracts. While the bioprospecting project does not intend to rely on such knowledge to identify species, it is still possible that a species of importance to the indigenous Fijian pharmacopoeia may be among the samples provided to SIDR for screening and eventual commercialization. While the provision is made for any such discovery to be subject to a royalty payment scheme, it might be in the interest of the local community and the country at large to either retain the right to patent such a find or receive a greater share of the profits arising therefrom.

PRIOR INFORMED CONSENT

The agreement between USP and Verata contains specific procedures for prior informed consent related to any research activity. In the application process the applicant must provide information on: all parties participating in the research and who is funding the research; what kind of materials and how much will be taken; what kind of research is to be done and what the purpose of the research is; and what the conservation status of the materials is. In addition, USP must

continue to keep Verata informed of all research carried out after the agreements have been signed. By the agreement, USP is responsible for informing Verata of all progress and involving them as much as possible in all phases of the contract negotiations and subsequent activity. The USP is required to notify Verata of any meetings involving SIDR–USP and USP–Verata agreements. The USP is required to provide free legal help to the Verata to advise them on any aspect of the negotiations and a representative of the project must be available at Verata Tikina Council meetings to inform Verata Council members about the project. To ensure that there are no misunderstandings or miscommunications all draft agreements must be translated into the Fijian language and distributed to the people of Verata for their consideration. Verata are to be notified of any meetings and will be given ample time to respond. There is also a stipulation in the agreement to include women's and youth groups in the project though no specific means to this end are provided.

The PIC articles of the USP–Verata agreement also provide for continued communication even after agreements have been reached. These stipulations are to ensure that Verata stay informed of all research progress and any publications or commercial benefits arising from them. Any new potential commercial activity from an extract must be fully discussed as at the commencement of research activities. A written report in Fijian and English is presented to Verata every three months which reports on materials collected and transported to SIDR, any research progress resulting from these collections, and any moneys received and disbursed. The agreement also requires that the USP hold workshops every six months in Verata *tikina* so that all stakeholders can meet and discuss the progress of all ongoing research activities.

DISTRIBUTION OF BENEFITS

Expected benefits to USP to be generated by the USP–SIDR bioprospecting venture are:

- 60% of third party extract licensing fees of £15 per sample (1 gram of prepared crude alcoholic extract or 100 grams of dried plant part) per month for maximum periods of 12 months
- Fees for re-supply of samples generating further interest ("usually" £2,000–£2,500)
- 60% of net income accrued by SIDR through commercialization by a third party, including royalties
- Joint research (expected to improve USP's capacity)
- Joint patents on any in-house discoveries.

Benefits to the resource owners, i.e. the *tikina* of Verata, are specified in the separate USP–Verata contract as follows:

- 100% of the portion of extract license fees received by USP during the period of the NPDC project (1 January 1997–31 December 1998), less the costs of extraction and transportation thereafter
- Training of "approximately" six people in collecting and preparing samples, six people in methods of biodiversity monitoring, and six people in methods of socioeconomic monitoring
- Management of small village-based enterprises
- Six monthly community-wide workshops in resource management and community development. In addition, any further financial benefits arising from the USP–SIDR

bioprospecting venture are to be shared between USP, the *tikina* of Verata, and the Fijian government "on an equitable basis to be negotiated."

While the proportionate sharing of license fees among SIDR, USP, and Verata are clear, the contract does not specify the exact amount to be expected. Based on existing relationships of SIDR to third parties, however, the license fees to be returned to Verata are expected to amount to approximately US \$105,000, to be held in a community trust.

In sum, the benefits arising from the bioprospecting venture can be expressed as a multi-level sharing arrangement. At the community level, benefits include a modest cash sum, which may increase should royalties be generated, education in conservation and community development, and support of village-based enterprises. At the national and Pacific-regional levels, benefits include potential financial remuneration and the improvement of the capacity of the University of the South Pacific, which serves twelve Pacific nations, in natural product drug screening techniques.

It is important to note, however, that the NPDC project is broader than the contents of the legal agreements between USP, SIDR, and the *tikina* of Verata. In addition to the above, a marine area conservation plan, screening of biological compounds for activity against Pacific region diseases, and the international marketing of products such as kava (*Piper methysticum*), nuts, and fruits constitute a range of benefits to the community and nation that ought to be taken into account—if they are successfully implemented.

COMPLIANCE MECHANISMS AND CONFLICT RESOLUTION

According to the USP–SIDR contract, any dispute between the parties that cannot be resolved bilaterally will be subject to the Rules of Arbitration of the International Chamber of Commerce and will be settled in London. The agreement is to be honored and enforced according to English Law.

The agreement between USP and Verata, meanwhile, is subject to the authority of the office of the Permanent Arbitrator in Suva, Fiji, though any activities undertaken are also subject to the approval of the traditional authority of the Paramount Chief of the *tikina* of Verata and the Verata Tikina Council.

CONSERVATION AND SUSTAINABLE USE

Both the USP–SIDR and USP–Verata contracts specify that the natural environment of Verata will not be adversely affected by the collection of samples. The USP–Verata contract, meanwhile, further commits to the implementation of community-based conservation projects, if necessary, to preserve species and habitats.

In fact, such community-based conservation measures have actually been taken in some areas of the fishing grounds and reef habitat in a novel reinterpretation of a pre-colonial taboo system, banning extraction in certain areas in order to allow the recovery of certain species of commercial value. As an indicator, preliminary biological monitoring conducted as part of the

NPDC project shows a substantial increase in the population of the *kaikoso* clam, a commercially exploited food species. Meanwhile, there have been, to our knowledge, no reports of environmental degradation due to bioprospecting. This is not surprising due to the small quantities of each species needed for preliminary testing by SIDR.

CONCLUSION

The case of the NPDC project in Fiji is an interesting example of how local, regional, and international institutions, such as local community structures, NGOs, universities, and government bodies, can work together to form a locally-tailored response to the objectives of an international convention such as the CBD. As such, it is a potentially useful model for other countries trying to formulate their own policies, taking into account that the political realities and ownership issues of every area will be different. In attempting to monitor the effects of the entire project in terms of socioeconomic development and conservation, the NPDC project is among the most extensive endeavors to create an equitable access regime to date.

BIOPROSPECTING UNDER PRESIDENTIAL EXECUTIVE ORDER 247 IN THE PHILIPPINES¹⁴³

In 1995, in response to the increasing pressure on the country's biological diversity, the Philippine government issued Presidential Executive Order 247 (EO 247) aimed at setting up a framework for regulating the prospecting of biological and genetic resources.¹⁴⁴ Since then, the Philippine government has approved only two of 37 applications for access to genetic resources by commercial and academic interests. The first was a commercial research agreement (CRA), signed in July 1998, between the Marine Science Institute of the University of the Philippines (UP-MSI), the Department of Agriculture (DA)¹⁴⁵ of the Philippines, and the University of Utah, USA,¹⁴⁶ The second was an academic research agreement (ARA), signed in 1999, between the University of the Philippines (UP)¹⁴⁷ and the Philippine government (ARA 99).

The CRA 98, entitled "Anticancer Agents from Unique Natural Product Sources" allows Parties "to collect from certain areas in the Philippines marine organisms as a source of extracts and compounds with potential anti-cancer activity which shall be exported to the United States for evaluation of the presence of the stated medicinal or pharmacological content." The ARA 99 was provisionally approved in March 1999, and is aimed at regulating the access by the UP to genetic resources over the entire territory of the Philippines.

Because the final version of ARA 99 has not been signed at the time of writing, we focus our discussion on CRA 98, with occasional references to ARA 99.

REGULATORY ENVIRONMENT

EO 247 was signed into law on 18 May 1995 as a response to a non-governmental initiative aimed at implementing the Convention on Biological Diversity. It provides a legal framework for bioprospecting and represents one of the first attempts by a nation to formally regulate access to biological diversity. In June 1996, the Department of Environment and Natural Resources issued

Department Administrative Order No. 20 (DAO 96-20) that sets forth the rules and regulations governing the implementation of EO 247 and provides details about the application and review process necessary for Parties seeking access to genetic resources. DAO 96-20 also established the Inter-Agency Committee on Biological and Genetic Resources (IACBGR) to review applications for access to genetic resources. Included in the IACBGR are not only representatives from various government agencies but also a representative from a non-government organization and a member of a "people's organization" representing the interests of indigenous communities.

EO 247 distinguishes between Academic Research Agreements, or ARAs, entered between universities, academic institutions, governmental agencies and inter-governmental agencies for the purpose of academic and scientific research, and Commercial Research Agreements, or CRAs, entered into between private parties, corporations or foreign international entities for commercial purposes. According to EO 247, the minimum requirements for an ARA should be much broader and general in character than the requirements for a CRA. This is an implicit recognition that parties interested in accessing genetic materials often have different goals and should therefore be subject to different requirements.

Where appropriate, any CRA or ARA must also comply with other state regulations, including the Indigenous People's Rights Act of 1997 and the National Integrated Protected Areas System Act of 1992.

The main objectives of the CRA 98, approved for three years in July 1998, are: (1) to collect marine organisms from different habitats within the Philippine Archipelago; (2) to isolate active metabolites and to determine their structure; and (3) to perform systematic inventories of biodiversity of the various habitats within the Philippine marine ecosystem. The original terms and conditions of the proposed agreement were reviewed on 26 January 1998, at the 10th meeting of IACBGR. Finally, on 9 June 1998, at the 11th meeting of the IACBGR the agreement was approved in principle.

The ARA 99 was provisionally approved in March 1999 by the IACBGR. This is the first ARA developed in the Philippines and is designed to be a model for subsequent ARAs. The multi-party agreement is a culmination of two years of preparatory work. The aim of the ARA 99 is to regulate UP's access to genetic resources over the entire territory of the Philippines. Hence, ARA 99 represents several different sub-agreements under one umbrella agreement. According to EO 247 and DAO 96-20, if the academic activities result in identifying certain genetic resources that have commercial potential, then a special CRA must be developed.

STAKEHOLDERS

The CRA 98 was negotiated between the University of Utah, USA, which is the Principal Collector (PC); the UP-MSI, which is the Co-collector (CC), and the Philippine Department of Agriculture (DA), which assists in the review and evaluation of proposals in the areas of agricultural, fishery, and other resources within its jurisdiction. Special attention was given to the collaborators of the PC and CC that may acquire, for non-commercial purposes, samples of the

material collected under the CRA 98. Indigenous and local stakeholders are also acknowledged in the discussion of PIC.

ARA 99 involves the following Parties: (1) UP, the principal collector; (2) the Philippine Department of Environment and Natural Resources (DENR),¹⁴⁸ which is the primary government agency responsible for the implementation and enforcement of EO 247 and DAO 96-20; (3) the Philippine Department of Agriculture (DA); d) the Philippine Department of Science and Technology (DOST),¹⁴⁹ which is involved in the review and evaluation of proposals for bioprospecting activities; and e) the Philippine Department of Health (DOH),¹⁵⁰ which has the authority to approve Research Agreements for pharmaceutical and medicinal research and development for commercial and academic purposes. Indigenous and local stakeholders are also acknowledged in the PIC section of the agreement.

PROPERTY RIGHTS

Article XII of the Philippine Constitution states that the Philippine government owns and has full control and supervision of the wildlife, flora and fauna within its territory. However, according to EO 247, the Philippine government also recognizes the "rights of indigenous cultural communities/indigenous peoples (ICC/IPs)¹⁵¹ and other Philippine communities to their traditional knowledge and practices when this information is directly and indirectly put to commercial use." According to The Indigenous People's Rights Act of 1997, academic research activities within the ancestral domains of indigenous communities¹⁵² must be in compliance with the specific state regulations pertaining to ancestral domains.¹⁵³ ICCs/IPs are entitled to the recognition of the full ownership and control and protection of their cultural and intellectual rights.¹⁵⁴

In both CRA 98 and ARA 99, the ownership of all the materials¹⁵⁵ remain with the Republic of Philippines. Under CRA 98, a complete set of all specimens is to be deposited at the UP-MSI, which will make arrangements with the National Museum of Philippines (NMP)¹⁵⁶ regarding the requirement for holotypes.¹⁵⁷ In addition, when materials collected under the CRA 98 are transferred to third parties, ownership of the materials is defined explicitly by CRA 98 and must be accompanied by a standard Material Transfer Agreement (MTA). Data, documents and other materials are required by law to remain confidential for purposes of acquiring intellectual property rights, and cannot be disclosed until after the rights to the inventions become vested and are protected.

PRIOR INFORMED CONSENT

EO 247 states that access to biological and genetic resources will only occur with the PIC of the local indigenous communities according to the customary laws of the community. Section 7 of the DAO 96-20 provides in detail the procedure for obtaining PIC for both ARAs and CRAs. Furthermore, Chapter VI of The Indigenous People's Rights Act of 1997 states that access to indigenous knowledge related to the conservation, utilization and enhancement of biological and genetic resources shall be allowed within ancestral lands and domains of the ICCs/IPs "only with a free and prior informed consent of such communities, obtained in accordance with customary laws of the concerned community."

Under CRA 98, PC and C-C must secure the PIC of the indigenous peoples and/or local communities and/or Protected Areas Management Board in the areas of collection scheduled for the first year, *before* the signing of CRA 98. For the second and the third year of the agreement, the relevant PIC must be obtained at least 30 days prior to the actual collection date. According to the CRA, disclosure of traditional knowledge shall be made only with the prior informed consent of the indigenous people or local community concerned.

For MTAs under the CRA 98, a third party must consult and secure a written consent from the University of Utah/UP-MSI for the IPR to inventions developed from the materials and before attempting to license or otherwise develop the intellectual property. Written consent should be embodied into a separate agreement signed by the parties indicating, *inter alia*, ownership, licensing or royalty provisions. In addition, the third party must consult with the University of Utah/UP-MSI before attempting to publish scientific manuscripts or reporting research performed on the materials. Finally, the third party must share the written draft of manuscript(s) before publication with acknowledged contributions of Parties to the original CRA 98.

According to ARA 99, PIC may be obtained through the mechanisms established by the EO 247 and DAO 96-20, depending on the area where research is going to take place (public, private, community, or indigenous lands).

DISTRIBUTION OF BENEFITS

According to DAO 96-20, benefit sharing refers to "the sharing of results of bioprospecting activity and benefits arising from the utilization of commercialization of the biological or genetic resources fairly and equitably" Possible benefits include payment for specimens, royalties, sharing of data, technology transfer, capacity building, and joint research. Specifically, EO 247 requires that the agreement contain a provision for the payment of royalties to the Republic of the Philippines, local or indigenous communities, and individual parties or designated beneficiaries if commercial use is derived from the genetic or biological resource. In addition, Philippine scientists must be actively involved in the research and collection processes if the commercial collector or its principal is a foreign person or entity. In certain cases, the Party shall be required to donate some of the equipment used in conducting the research to a Philippine institution. Finally, an agreement must include a special provision regarding endemic species. According to the DAO 96-20, a Party developing a technology from research of a Philippine endemic species must make the technology available to the Republic of the Philippines without charging royalties.

Under CRA 98, upon approval of the agreement, a bioprospecting fee in the amount of P10,000.00 (ten thousand pesos) ¹⁵⁸ must be paid by the PC/C-C to the IACBGR for the duration of the agreement. It is unlikely that there will be a significant impact on the environment from the proposed activities under the agreement. Therefore, only a minimal performance bond no greater than P10,000.00 will be required, which shall be returned upon the termination of the agreement, provided that the PC or C-C has not violated any of the provisions of the agreement.

Parties to the CRA 98 agree to the equitable sharing of benefits, direct or indirect, short or long-term, including, but not limited to direct assistance, technology transfer, profit sharing, and co-ownership of intellectual property. All product discoveries derived from the materials collected under the CRA 98, their improvements, or their use shall be made available to the Philippine government and local communities concerned. The principal investigator/co-investigator shall provide the means to make these discoveries and/or inventions, available to the extent that it will not prejudice or render useless potential or local existing applications of intellectual property rights. When the discoveries are made from Philippine endemic species, the principal collector shall make available through the UP, the use of such discoveries.

Either PC, C-C, or the third party can obtain intellectual property rights, and/or commercialize materials and/or technology derived from them. When such intellectual property rights exist, a separate agreement shall be made among the PC, C-C and the third party for sharing the royalties, other benefits and technology derived from the collected materials.

When any invention, license, royalty, or other commercialization of any material occurs, 5% of the net revenue¹⁵⁹ received by the PC/C-C will be paid by the PC/C-C to the DA (the Integrated Protected Areas Fund if the materials come from a protected area; the concerned indigenous people or local community who gave the PIC; or persons who provided such materials from private property). The remaining balance of such net revenue will be shared equally between the PC and C-C.

In contrast, given the academic nature of ARA 99, only non-monetary benefits are discussed in the agreement, including training and information-sharing in the form of seminars, published reports, and collection protocols. If potential for commercial applications are discovered, monetary benefit-sharing arrangements will be included in the development of a new CRA.

In defining the rights and obligations of the parties, the CRA 98 emphasizes the technology-transfer responsibilities of the PC to the C-C with regards to the development and evaluation of the materials, and/or their derivatives and by products.

Joint obligations of PC and C-C include allowing Philippine citizens or government entities unrestricted access to the materials deposited in any *ex situ* depository or gene bank. Through its activities related to the agreement, the co-collector must develop an education program on resource conservation and environmental protection specially focused on the community where the collections are to be made. The C-C shall also help train government representatives in taxonomy or natural products chemistry through short-term internship programs. To provide benefits to the communities, the C-C must conduct an information campaign on the protection/conservation of coastal resources and their value. In addition, if inventions are derived from the use of the materials, the PC/C-C must provide training in a marine-related discipline if there is a qualified candidate from the community.

An important element of the CRA 98 is a protocol for dealing with materials collected unintentionally. No later than a year after the scheduled collection, the PC or C-C must submit a detailed list of identified species not included in the collection list of the CRA 98, as well as an inventory of unidentified materials.

COMPLIANCE MECHANISMS AND CONFLICT RESOLUTION

The IACBGR is in charge of the implementation of EO 247 and DAO 96-20. Specifically, the IACBGR ensures that the rights of indigenous communities are protected in the process of granting access to genetic resources.

Access agreements are monitored by the concerned government agencies according to a monitoring scheme developed by the IACBGR. There are two monitoring teams for each agreement, one monitors the implementation of the agreement within the country and the other monitors the research and commercialization done outside the country. A quarterly report must be submitted to the IACBGR by the Parties to an agreement indicating the type and quantity of biological or genetic material collected, and a semi-annual progress report must be submitted to the IACBGR describing the ecological condition of the study area and all research results. Finally, subject to a review by the IACBGR, the CRA must be renewed every three years and the ARA must be renewed every five years.

A party challenging a decision by an agency regarding approval of an agreement may appeal the decision to the Office of the President. A Party may only appeal the decision to the courts once all administrative remedies have been exhausted.

According to the DAO 96-20, the Philippine government has the right to unilaterally terminate the agreement and confiscate the collected biological and genetic specimens if there has been a violation of the terms of the agreement. By the same token, a Party may rescind an agreement if the other Party violates the terms of the agreement. In extreme cases, a Party found in violation of EO 247 may be subject to criminal penalties pursuant to existing Philippine laws.

Under the joint obligations of the CRA 98, the PC/C-C must comply with all the applicable laws and regulations of the Republic of Philippines and the United States. Any controversy or dispute related to the agreement which cannot be settled by mutual accord between the parties, must be settled by arbitration.

The Department of Agriculture (DA) obligations include monitoring the research activities in order to determine adherence to the provision EO 247, DA 96-20 and CRA 98. The PC and C-C must submit a copy of the collection reports to the field office of the DA Fisheries Office nearest the collection site. They must also provide the DA with a complete list of institutions, genebanks and other depositories where materials, data, and documents have been placed. The DA reserved the right to suspend or stop any collection or research activity if the PC or C-C does not follow the prescribed PIC process.

Willful violation by the PC or C-C of the terms and conditions of the Agreement will result in the cancellation of the agreement, the confiscation of the materials in favor of the Philippine government, and the imposition of reasonable penalties as provided under Section 10 of EO 247. The PC may rescind the agreement in case of bankruptcy, security problems and *force majeure*, provided that, in the case of bankruptcy, all bonds are forfeited and all equipment and materials and related documents transferred to C-C and other Philippine institutions.

SUSTAINABLE USE AND CONSERVATION

Systematic inventories of the biodiversity of various habitats within marine ecosystems, conducted under both research agreements are important for proper management and conservation of the Philippine marine environment.

Under the CRA 98, the potential impact of the proposed activities on the environment is considered to be minimal. Only the kind and quantity¹⁶⁰ of materials listed in the agreement's attachments can be collected, with collection carried out only in the designated collection areas. Joint obligations under CRA 98, requiring the PC and C-C to desist from collecting materials in areas prohibited by law except when allowed to do so by the appropriate regulatory agency. Quarterly reports describing the kind and quantity of materials collected and semi-annual reports describing the ecological conditions of the study area and species reports must be submitted by the PC and C-C to the IACBGR.

The technology transfer and benefit-sharing provisions of the CRA 98 aim to promote socioeconomic sustainability.

CONCLUSIONS

As any other reviewed case, research agreements in the Philippines have attempted to mitigate four major obstacles (see Chapter II) that stand in the way of successful implementation of biodiversity conservation, sustainable use, and equitable benefit sharing—the main objectives of the CBD. The special nature of genetic resources has been addressed in the agreements by having specific provisions about their comprehensive geographic scope, intellectual property rights, and unlimited access to *ex situ* collections of the materials. Specific provisions about ownership of the materials, MTAs, and patenting of the inventions deal with defining ownership and tenure of genetic resources. Technology transfer and training of local staff deal with the inadequacy of local institutional capacity. Finally, different stakeholders, from local communities to Protected Areas Management Board are defined and the mechanisms for ensuring their consent are outlined.

Because of the recent nature of CRA 98 and ARA 99, it is premature to evaluate how effective they are in achieving CBD's objectives. As written, CRA 98 is a comprehensive document that addresses all the main points of the CBD and Philippine state legislation. It is envisioned that both agreements will be used as models for regulating future access to genetic resources in the Philippines.¹⁶¹

THE YELLOWSTONE–DIVERSA AGREEMENT IN THE UNITED STATES¹⁶²

In the United States, the practice of bioprospecting on public land is well established and has, in some instances, yielded substantial profits to biotechnology and pharmaceutical companies.¹⁶³ Until very recently, however, access to genetic resources on US public lands occurred with little regulation and scant consideration of issues of ownership and benefit sharing. Governed by "a

patchwork of laws [that has] resulted in a primarily 'open' access system,"¹⁶⁴ the US genetic resource access regime is inadequate to protect resources and share benefits. The development of the CBD,¹⁶⁵ growing awareness of new practices elsewhere—most notably in Costa Rica—and the loss of enormous potential profits from biotechnological applications have exposed this shortcoming in US domestic policy concerning access to and use of genetic resources on public lands. The issue has been raised to the public light by an agreement between Yellowstone National Park and the Diversa Corporation to prospect for genetic resources in the geothermal waters of the Park.

Signed in August 1997, the Yellowstone–Diversa agreement is notable for many reasons. First, it is the first bioprospecting contract on US soil,¹⁶⁶ and is therefore an important test of the efficacy of existing legislation in complying to the CBD and fulfilling its objectives. Second, it is the first instance in the United States of an attempt to address the issue of the sharing of benefits arising from the commercial development of genetic products discovered on public lands, bringing into sharp focus questions surrounding equitable distribution. Third, the agreement brings to light a dichotomy between the "protected areas" and "sustainable use" conservation strategies which may shed new light on the difficulties the United States may have in fulfilling the mandate of the CBD. Finally, debate over the agreement illustrates in a broad sense the multi-faceted conflict between factions opposing and favoring the growth of the biotechnology industry on grounds both scientific and ideological.

As a result of these conflicting viewpoints on conservation and biotechnology, the Yellowstone–Diversa agreement was challenged in March 1999 by a federal judge in response to a civil suit.¹⁶⁷ The court's decision resulted in the suspension of a Collaborative Research and Development Agreement (CRADA) between the Park and Diversa Corporation, the mechanism through which bioprospecting benefits are shared with the Park. The research permit, meanwhile, is unaffected, allowing Diversa to legally continue its bioprospecting exercises. In a 29 March 1999 press release, the Diversa Corporation announced its intention to continue to honor the conditions of benefit sharing laid forth in the CRADA, thereby ensuring the continuation of the collaborative project. While the legal mechanism employed to challenge the agreement was a call for a standard environmental impact assessment to ensure the proper protection of the Park's natural resources, it would appear that the underlying issues motivating opponents to the arrangement are far more complex.

Although bioprospecting has been conducted in Yellowstone National Park since the first research permit was issued in 1898, interest increased substantially following the development of the heat-resistant enzyme Taq polymerase, derived from the bacterium *Thermus aquaticus*, which survives high temperatures in the hot springs and geysers of the Park. Although the special qualities of *Thermus aquaticus* were originally discovered in 1966, Taq was patented by the Cetus corporation and sold for US \$300 million to the Swiss pharmaceutical corporation Hoffman Laroche in 1991. A key ingredient to the polymerase chain reaction (PCR) technique of duplicating DNA for biotechnological applications, the commercialization of Taq generates an estimated US \$200 million per annum.¹⁶⁸ Isolated, patented, and marketed prior to the CBD, Taq was removed from the public domain without compensation to the Park, to the government, or to the US citizenry. The substantial revenues generated by the product did not escape notice, however: with new conceptual grounds laid forth by the CBD, and through best practices such as

the Merck–INBIO agreement in Costa Rica the US bioprospecting field changed dramatically in 1997 with the Yellowstone–Diversa deal.

REGULATORY ENVIRONMENT

In the United States, access to genetic resources on public lands is currently regulated under a complex of pre-existing legal instruments that were not specifically designed to comply with the goals of the CBD. While, if properly interpreted and applied, they may fulfill some of these objectives, we shall see how lack of specific legislation led, in the Yellowstone case, to the opportunity for successful opposition by groups whose interests are not necessarily closely related to the precise realities of the specific case at hand.

The Yellowstone–Diversa agreement relies primarily on two relevant pieces of legislation: the National Park Service Organic Act and the Federal Technology Transfer Act. In *Edmonds Institute et al. v. Bruce Babbitt*, the same legislative mechanisms were used to challenge the Yellowstone–Diversa benefit-sharing arrangement, along with interpretations of the National Environmental Policy Act (NEPA), the Yellowstone National Park Organic Act, and the Administrative Procedure Act.

The National Park Service Organic Act governs the collection of research specimens on national park land, locating authority to evaluate and issue collection permits at the level of the individual park superintendent. Issuance of such permits is subject to the submission of a detailed "Statement of Work," describing in detail the objectives and methods of collection activities.¹⁶⁹ The "Research Specimen Collection Permit" does not grant exclusive or proprietary rights to the researcher, and does not constitute a sale of material or knowledge derived therefrom.¹⁷⁰

The Federal Technology Transfer Act (FTTA) was enacted in 1986 in response to congressional concern that research funded by federal agencies did not result in the return of commercial benefits arising therefrom the laboratories of origin. Under the FTTA, the CRADA is the mechanism governing the sharing of research results and benefits between government organizations and private sector researchers. In the Yellowstone case, application of the FTTA and the formation of a CRADA relies on the interpretation of the term "laboratory" to include national parks and even, perhaps, all federal lands.¹⁷¹

The NEPA, meanwhile, requires that any federal action "significantly affecting the quality of the human environment" be subject to a prior environmental impact statement (EIS) or environmental assessment (EA). The purpose of the EIS and EA is to ensure transparency so that the public has the opportunity to review and participate in the process of evaluating the desirability of a project from an environmental perspective. However, "categorical exclusion" from the EIS/EA requirement is possible; in order to claim such an exclusion, Yellowstone National Park defines the bioprospecting activities of Diversa as "day-to-day" resource management.

In addition to these laws, applicable US laws governing the fate of information derived from bioprospecting at Yellowstone are patent and copyright law, which will not be covered here.

Recently, an interagency panel has attempted to formulate an interim policy on access while awaiting a fixed legislative response. While focusing mostly on the collecting of botanical resources, the panel is working to interpret and apply the aspects of genetic resource access and benefit sharing covered by the CBD.¹⁷²

STAKEHOLDERS

Yellowstone National Park, the Diversa Corporation, the World Foundation for Environment and Development (WFED), the National Park Service, and the people of the United States may be considered to be the primary stakeholders in the Yellowstone–Diversa agreement. In addition, we will consider as stakeholders in the arrangement the plaintiffs in the case brought against Yellowstone, which culminated in the suspension of the CRADA in March 1999.

Yellowstone Park initiated the Diversa project by approaching the various corporations already conducting bioprospecting activities in the Park. The National Park Service was interested in using Yellowstone as a "guinea pig" case to establish protocol for all protected parks in the United States. When Diversa responded positively, John Varley, Director of the Yellowstone Center for Resources, began to research cases of access to genetic resources around the world, identified best practices, and scrutinized the CBD to establish a means to ensure that the Yellowstone venture would represent a progressive arrangement. In 1995, Varley contacted Preston Scott of the World Foundation for Environment of Development. Scott, a lawyer interested in issues surrounding access to biological resources, arranged an educational trip to Costa Rica in January 1996 to familiarize Yellowstone authorities with the activities of INBio and Merck Pharmaceuticals, Inc.

Following the agreement between Diversa and Yellowstone in 1997, opponents to the deal began to take action. The four plaintiffs in the case, *Edmonds Institute et al. v. Bruce Babbitt*, are the Edmonds Institute (EI) in Washington State, the International Center for Technological Assessment (ICTA) in Washington, DC, the Alliance for the Wild Rockies (AWR) in Montana, and an individual, Philip Knight. Together, they represent interests not specifically taken into account in the Yellowstone–Diversa agreement, due to divergent ideological backgrounds. The EI and ICTA are non-profit organizations who staunchly oppose IPRs on biological resources as well as the biotechnology industry in general. The AWR and Philip Knight (a guide and nature-lover) represent the strict conservationist view, opposing any commercial activity in national parks whatsoever. In effect, these plaintiffs are stakeholders in the issues of biotechnology, intellectual property rights, and conservation, and may be using the highly visible Yellowstone–Diversa agreement to garner publicity and support for their political agendas.

PROPERTY RIGHTS

Tangible property

Yellowstone National Park may represent an ideal place to initiate a benefit-sharing arrangement because the issue of ownership is not in dispute. "Getting rules of ownership clear is a condition to any effective benefit-sharing program," Preston Scott of the WFED states, pointing out that such clarity is not possible in many parts of the world where ownership of lands and resources is disputed. In the United States, such disputes exist as well, especially in the case where

outstanding claims by indigenous peoples have not yet been resolved. It is true, however, that the ownership of Yellowstone National Park appears quite straightforward from a legal perspective.

Yellowstone National Park is administered by the National Park Service under the authority of the federal government's Department of the Interior. While other types of federal lands are managed for forestry, mining, and other types of extractive activities, park lands are managed for conservation and limited recreational activities. While the removal of any material from a National Park is generally prohibited, a "specimen collection permit" for the purposes of scientific research may be obtained from the National Park Service. The permit is issued on the authority of the park superintendent to "an official representative of a reputable scientific or educational institution or a State or Federal agency for the purpose of research, baseline inventories, monitoring, impact analysis, group study, or museum display, when the superintendent determines that the collection is necessary to the stated scientific or resource management goals of the institution or agency."¹⁷³ Only permits requiring an environmental assessment or impact statement need to be reviewed at the regional level of the Park Service.

The specimen collection permit does not transfer ownership of the specimens collected to the collector. In fact, in the case of the Yellowstone–Diversa arrangement, ownership of the physical material collected remains the property of the Park. The permit is a temporary license in effect for the duration of the permit.

Intellectual property

Yellowstone recognizes a distinction between sale or commercial use of natural products and research results that may generate revenues. The former implies commercial transfer of physical resources, which is prohibited; the latter concerns applications of knowledge derived from study. In addition, "Specimens and data derived from consumed specimens" must be "made available to the public and publications resulting for a research specimen collection permit shall be filed with the [park] superintendent."¹⁷⁴

In the case of the Yellowstone–Diversa venture, an explicitly commercial venture, the FTTA was invoked to allow the results of research to be used for commercial purposes. While the specimen collection permit obtained by Diversa expressly prohibits commercial use, a second agreement formed under the FTTA, the CRADA, apparently allows the parties to bypass the issue of public tenure, effectively allowing the privatization of the intellectual material collected.

PRIOR INFORMED CONSENT

Under the CBD, the user of the resource is required to provide information to the state (here represented by the park service) prior to the issuance of a permit.¹⁷⁵ In the Yellowstone–Diversa agreement, prior informed consent (PIC) between the contracting parties may not be a major issue: it was the park service that initiated the process with the express intent of discovering applications for products derived through research on thermophilic organisms.

The Yellowstone–Diversa agreement was not examined from the angle of PIC, though it is at least partially covered through several aspects of the specimen collection permit and the CRADA. The permit application process requires a description of the research program

identifying what types of organisms are wanted, for what purpose, and the means of collecting. The CRADA, meanwhile, contains a patent notice requirement, which is not subject to rejection by the owner. It is therefore prior information, rather than prior consent. A further protection for the park, however, is a clause in the CRADA which specifies that the corporation cannot sell a patent without the Park's consent to ensure that any new patent owner must take on the same royalty payment arrangements as the original owner of the patent.

DISTRIBUTION OF BENEFITS

The Yellowstone–Diversa contract provides for annual payments from Diversa to Yellowstone of US \$100,000 for five years for sample collecting and collaborative research with the Yellowstone research facility as well as "in-kind services and resources valued at US \$375,000." While the exact terms regarding the sharing of royalties earned by Diversa through eventual commercialization remain confidential, the corporation and the park have made reference to a schedule providing for returns of 0.5 to 10% of proceeds resulting from any commercial exploitation of products developed from organisms discovered in the park.

According to accounts of the contract, all proceeds are to be channeled to the Park for the purposes of conservation and enhancement of research facilities. This may be considered inequitable for the following reasons: first, if a product of substantial economic return such as Taq occurs, the Park may eventually receive more than is needed to fulfill its primary purpose, which is preservation of biodiversity. In such a case, the practice of charging entrance fees to the general public might need to be reconsidered. Second, the organisms in Yellowstone's hotsprings may exist elsewhere, in which case joint ownership ought to be considered. If the returns are negligible or non-existent, on the other hand, we need to ask how much the operation costs the Park in terms of labor and capital: US \$100,000 may not be sufficient to recover the costs of the project.¹⁷⁶

COMPLIANCE MECHANISMS AND CONFLICT RESOLUTION

As mentioned above, access to resources on park land is governed by a permit system that is largely subject to the authority of individual park superintendents, except where the activity is disruptive enough to require an environmental impact statement.

Resolution of conflict arising between Yellowstone National Park and the Diversa Corporation is provided for under Article 13 "Disputes" of the CRADA, which states "any dispute arising under this CRADA which is not disposed of by agreement of the parties shall be submitted jointly to the signatories of this CRADA," and "If the signatories are unable to jointly resolve a dispute within a reasonable period of time after submission of the dispute for resolution, the matter shall be submitted to the Director of the NPS, or his designee, for resolution." Prior to reaching resolution, activities allowed under the CRADA are to continue as usual.

SUSTAINABLE DEVELOPMENT AND CONSERVATION

There are two divergent perspectives as to the effects of the Yellowstone–Diversa arrangement in terms of sustainable development and conservation. One perspective concerns the effect of the

arrangement on the park, the other the secondary effects of the arrangement on geographically removed or widespread areas.

First, it would appear that sampling of bacterial organisms from Yellowstone's waters is not, in itself, an ecologically detrimental activity. From the Park's perspective, the sampling process does not affect conservation efforts. Stakeholders interested in a strict interpretation of conservation as prohibiting all commercial activities as a matter of principle, such as the plaintiffs AWR and Philip Knight, may disagree.

The two other plaintiffs in *Edmonds Insitute et al. v. Bruce Babbitt* are concerned with the larger issues of intellectual property rights and biosafety—in effect, with what happens to the information derived from the samples after they are removed from the park. This is not directly relevant to Yellowstone National Park, since it concerns "what comes out [of Diversa's lab], not what goes in."¹⁷⁷ The Edmonds Insitute and the International Center for Technological Assessment, however, are concerned with the issue of sustainability on a wider level than Yellowstone National Park. While some might dismiss out of hand the concerns of these stakeholders, it is interesting to note that the scientific community is not in agreement concerning the widespread application of biotechnology. It might therefore be relevant to consider the ramifications of a change in policy concerning the use of US public resources toward an activity that is not necessarily desired by the entire community that owns the resources.

CONCLUSION

The Yellowstone–Diversa agreement is significant in that it has stimulated a debate which will help to define how, if ever, the US works to reconcile existing legislation on access to public resources, intellectual property rights, indigenous property rights, and bioprospecting policy with the goals of the CBD. In addition, it marks the beginning of an apparent shift in US conservation policy from total protection to limited use for economic benefit, which is certainly a step in the direction of the CBD. However, the issues of respecting the rights and interests of all stakeholders and the equitable sharing of benefits are problematic in the US, where decision making is highly decentralized due to the structure of the Department of the Interior.

CHAPTER IV. ANALYSIS

Each of the cases described in the previous chapter is defined by certain unique attributes. These attributes include the way in which stakeholders are defined, property rights are determined, benefits are shared, consent is obtained, compliance is enforced, and biodiversity conservation is attained. At the same time, the cases are united by the common goal of implementing the three objectives of the CBD: conservation, sustainable use, and equitable benefit sharing. Understanding how effective the cases are in achieving these objectives requires moving beyond the case-specific analysis to encompass a broader interpretation of common themes, trends, and unresolved issues.

Chapter IV examines the seven cases to discover which characteristics make them similar, and which set them apart. The themes that have been the bases for the analysis of each case study in the previous chapter are the units of the cross cutting analyses presented here.

STAKEHOLDERS

The CBD prescribes that when benefits are generated through access to genetic resources they must be fairly and equitably shared among people who hold direct stake in these resources. In order to implement this mandate, definition of the term "stakeholder" is required. Who are the stakeholders in instances of access to genetic resources and traditional knowledge, what are their respective rights, and what is at stake? Additionally, the issue of stakeholder representation must be addressed in access legislation and regulation. Stakeholders include individuals, community groups, organizations, or institutions that will somehow be affected by an instance of access to genetic resources and the subsequent benefit sharing arising from such access. In the seven case studies we have presented various types of access to genetic resource agreements, however, the parties to an agreement are not necessarily representative of the entire range of stakeholders in a country.

We can divide stakeholders into two categories: direct and indirect. Direct stakeholders are those who stand to benefit or be harmed directly by the terms and conditions of a specific case of genetic resource exploitation. These would, most obviously, include resource owners and resource users. In general, we expect direct stakeholders to be parties to any formal bioprospecting agreement or contract. Indirect stakeholders, are those who are interested in the outcome of genetic access agreements in general but are not directly implicated in the negotiation or implementation of a specific agreement. The largest group of indirect stakeholders in all instances consists of all of humanity,¹⁷⁸ which may have stake in the preservation of biological diversity at large but may not be quantifiably affected by the extraction of samples from any particular locale. NGOs interested in specific environmental or human issues may be seen as representing the interests of various groups, with causes ranging from poverty alleviation to animal rights. In the case of pharmaceutical bioprospecting, a group of people suffering from a specific ailment may be considered indirect stakeholders, although the details of any specific agreement would be beyond their broad interest.

Chapter II presents six levels of stakeholder involvement in access to genetic resources. These are (1) nation states, (2) local communities, (3) industry, (4) NGOs, and (5) scientists conducting

basic research. It is also suggested there that the priorities of different stakeholders in their agendas for genetic resource use vary widely. These six levels and their priorities, represented variably in agreements and instances of access to genetic resources, are described below.

Government participation in access agreements is becoming more common with the implementation of national and state access laws whereby state agencies are compelled to process requests for access and monitor compliance. Typically, these state agencies are offices of the Ministry of Natural Resources or Ministry of Science and Technology and are considered parties to an agreement. In cases where two agreements complete the access request loop, such as in the Merck–INBio/INBio–MINAE in Costa Rica or the NCI–UNIP/UNIP–SMA agreements in Brazil, the state agency is party only to the agreement involving permission for actual collection of resources.

In all of our cases, legislation specifically defines the state as a stakeholder in bioprospecting agreements. In some cases, there are specific mandates for the state to receive financial benefits in the form of royalties or up-front payments. In the USP–Verata case in Fiji the state is appointed as beneficiary of royalties through national law, and in Cameroon the 1994 Forestry Law assigns the state to receive royalties from ". . . the economic and financial spin-off resulting from their use . . . the rate and conditions of which shall be laid down . . . by an order of the minister in charge of finance . . ."

Institutions involved in collection or sample processing, either private or public, are most often direct parties in an agreement. Actors at this level are typically national scientific institutions—those doing the actual collecting and/or some level of processing of genetic resources, and industry companies—those receiving and evaluating the resource for product development. In many cases a national institution is doing the collecting for a contracting institution such as INBio does for Merck in Costa Rica or UNIP proposes to do for NCI in Brazil. In both of these cases the scientific institution stands to gain not only by receiving benefits directly from the foreign interest, but also by the opportunity to advance their scientific endeavors, be it conducting a national biodiversity inventory or collecting material for purely scientific analyses. In some cases a third party foreign scientist or institution is involved in collection alongside the national representative such as the case of the Missouri Botanical Garden collecting in Cameroon with the University of Yaounde for NCI.

If access to traditional knowledge or resources on indigenous or local community land is sought, indigenous populations or local communities usually will have a representative council or organization to negotiate in the interest of the community. Sometimes the state or an NGO represents these stakeholders. Indigenous and local communities are not always parties to a primary agreement for access to a nation's genetic resources, but their prior informed consent is in all our cases required in an additional contract or agreement. The same requirement holds for private property owners. Breaking this trend is the community of Verata in Fiji, which is the legal owner of the land and resources and—as such—is party to the Verata–USP contract.

Public citizens' stake in biodiversity conservation is often represented through international conventions and interest groups, or NGOs. An NGO may be named as a third party stakeholder in an agreement, as in the USP–Verata agreement in Fiji where the Biodiversity Conservation

Network is named as an interested stakeholder though it is not a direct party to the agreement. Additionally, the Rainforest Alliance is recognized as another party to this agreement "whose interest it is to promote the equitable distribution of benefits arising from natural resource exploitation around the world." In Colombia when the BioAndes application was proposed, the NGO *Grupo Semillas* voiced their concerns over the terms of the application by submitting a position statement to the request review committee, expecting to block a possible agreement.

As illustrated in the case studies, additional stakeholders may appear or stake a claim after an agreement or policy is implemented; and may or may not have been consulted or represented during the development of an agreement or regulation. In the Yellowstone–Diversa case concerned parties external to the agreement initiated a law suit attacking the benefit-sharing agreement between the corporation and the Park, aiming to stop bioprospecting activities. Their concerns were ethical in nature: two plaintiffs oppose commercial activity in national parks, while the other two oppose biotechnology and IPRs on biological resources.

Failure to properly identify stakeholders and satisfy their rights and interests in either the access policy development phase or agreement apparently thwarts the interest of equitable benefit sharing as required by the CBD, as illustrated in some of these cases. Consultation with special interest groups who may be stakeholders in an agreement, such as environmental NGOs, the scientific community, and indigenous groups and traditional communities during the development of legislation offers the most efficient way to incorporate their rights and interests into all agreements. In the extreme, stakeholders who have not been represented in the process of creating access policy or agreements may successfully impede or prevent access to the resource during agreement negotiations or implementation.

A lack of *a priori* stakeholder identification in the early agreements in Cameroon around the collection and research on *Ancistrocladus korupensis* resulted in conflict between actual stakeholders when potential benefits from access began to arise. This was a clear warning that the identification of all stakeholders must be made before the initiation of access and subsequent research and development. Also in the *A. korupensis* case the issue of stakeholder representation is illustrated. An early agreement between NCI and the University of Yaounde was dismissed by the Government of Cameroon on the grounds that the University did not have the authority to represent national interests. In the same vein, one of the questions that the PROBIO working group in São Paulo is grappling with is: who has the legal right to regulate access and distribution of benefits¹⁷⁹ In Brazil, will state legislation take precedence over federal legislation, or vice versa? This remains to be seen and will be a decision of the federal administration.

DEFINING PROPERTY RIGHTS WITHIN AGREEMENTS AND LEGISLATION

In the context of access to genetic resources we discern three discrete types of property rights associated with genetic resources. First, there is a "real property" right associated with the land and anything growing on or attached to the land including plants, animals, and other organisms that contain the genetic material.¹⁸⁰ Second, there is a genetic property right associated with the genes that are isolated from a genetic resource. Finally, there is an intellectual property right associated with the intangible discoveries made from use of the genetic material.

Article 15(1) of the Convention on Biological Diversity reaffirms a State's sovereign right to make and enforce laws regarding access to the genetic resources within its territory.¹⁸¹ In so doing, the CBD defers to the individual States the definition of the three types of property rights .

Tangible property rights

As noted in Chapter II, real property regimes vary widely between countries and are often a mixture of private property rights, state-owned property rights and communal property rights. The owner of private property typically has exclusive and absolute rights to the land. In contrast, government or community owned property is generally not restricted to any one individual's use or possession unless the government decides to grant individual tenure rights over the land.

In some cases, genetic property is attached to the real property containing the genetic resource. For instance, in the Yellowstone–Diversa case study, the US Government, as the owner of Yellowstone National Park, also maintained ownership of all the genetic materials taken from the park. Although this case involved state owned property, the genetic property would have been attached to the land even if the owner of the land had been a private party.

However, most of the case studies for this report involved agreements that did not attach the real property rights to the genetic property rights. For example, although the Philippines recognizes private property rights and claims by indigenous peoples to ancestral lands, the real property owner is not considered the owner of the genetic material. In both Philippine agreements, the government maintains ultimate ownership of all genetic materials. Likewise, in the INBio–Merck agreement, there is a distinction made between the actual genetic material, which belongs to the public domain, and the land containing the genetic resources, which belongs to the private property owner.

Nevertheless, most of the case studies represent agreements involving access to publicly owned lands, thereby eliminating the need to distinguish between private ownership of real property and government ownership of genetic material. For instance, in the Cameroon case, access was sought in the Korup Forest Reserve. Under the agreement, the Cameroon government, owner of the land, also retained ownership over all genetic and biological resources. Similarly, in the UNIP case study in Brazil, the company restricted its request for access to the Intervales State Park, therefore limiting the scope of the agreement to only state land where there was some certainty regarding property rights.

Intellectual property rights

Intellectual property rights (IPR) are unique in that they create property rights over intangible information created by human beings. In the context of genetic resources intellectual property rights are often defined and protected in the form of patents, plant breeders' rights (PBRs), trade secrets, copyrights, and trademarks. The underlying rationale for IPR systems is that they offer protection to new innovations and therefore create incentives for further investment in developing future innovations.

The flexibility of a nation in developing an IPR system is limited, at least among signatories to the GATT/WTO, by the TRIPs agreements. The TRIPs agreement sets a minimum standard for national protection of IPRs. TRIPs requires signatories to recognize patents on most products and processes. Nonetheless, there is an exception for patents of plants and animals: it is within the

nation's discretion to decide whether to recognize the patents. As noted in Chapter II, this may soon change since there is currently a move by many developed nations to require the recognition of patents on plants and animals.

In the case of genetic resources the nature of IPRs is even less clear. There are two different standards for allocating IPRs. Most of the agreements explicitly grant Parties the right to patent innovations derived from the research. Nonetheless, the standard for indigenous knowledge is less generous: in many of the agreements indigenous knowledge is recognized, but the knowledge is not granted protection by intellectual property rights. For example, in the INBio–Merck agreement the Parties have the right to apply for patents from innovations realized during the study. But a similar provision recognizing indigenous intellectual property rights was not included in the agreement despite a Costa Rican law that recognizes and protects the practices and innovations of indigenous peoples.

In many cases indigenous knowledge is not considered intellectual property because there is no national legislation protecting the rights of indigenous knowledge. For example, the BioAndes application would grant the company the right to patent any new products derived from the genetic resources. Although indigenous knowledge is mentioned in the first BioAndes application, there is currently no Colombian legislation recognizing traditional knowledge as intellectual property *per se*. Likewise, the NCI agreement in Brazil provides for joint patent protection for all inventions developed collaboratively by NCI and local employees. The agreement does not recognize intellectual property rights for indigenous knowledge, instead it defers to national legislation but currently no legislation exists in Brazil to provide intellectual property rights for such knowledge.

The Philippines may go farther than any country in its recognition of indigenous knowledge. The Philippine legislation governing access to genetic resources, EO 247, explicitly recognizes the rights of indigenous communities to their knowledge when it is used for commercial purposes. It also notes that the indigenous communities must first consent before research activities can take place on their ancestral lands.

As noted in Chapter II, the development of a comprehensive property rights regime is essential to successful genetic resource access legislation and agreements. Property rights ensure that the various Parties in control of the real property, genetic property or intellectual may be entitled to share in the benefits derived from the use of the genetic material. Nevertheless, as we have seen in the case studies, most countries are still attempting to define these various property rights in the context of access to genetic resource agreements and legislation. The relatively short conceptual history of genetic resources as pure genetic material has added to the confusion in this respect.

PRIOR INFORMED CONSENT

The CBD states that providers of genetic resources must be informed of how they are going to be compensated and what is going to be done with the resources in order to grant consent.¹⁸² All of the case studies presented here contain some kind of provision for prior informed consent. In practice, however, it has been difficult to determine the best way to inform all participants, especially if there are language and cultural barriers. Part of the issue is what kind of information

should be provided, and to what lengths the recipients should go to inform all participants. Moreover, bioprospecting is not a straightforward venture; what kind of benefits are generated may take years to ascertain, if ever, or may be completely different from what was intended at the beginning of the negotiation. Hence the advantage of flexibility in shaping the access agreements. The CBD calls for all stakeholders to reach mutually agreed terms for consent to be granted.¹⁸³ These issues are covered in all the cases presented above and the main points are discussed here.

Who should be informed?

All the case studies require some kind of consent from a state agency, though they vary in how much the state is involved and how much information they receive. The state agency in Costa Rica (MINAE) has broad guidelines within which INBio must be responsible but INBio does not have to gain consent from the government for every instance of access. In the Fiji case the Verata Council has significant autonomy in the negotiations although there is an application process through the Department of the Environment. The Yellowstone–Diversa case involves a government official, who is the park superintendent, but there is no oversight by any higher government body.

The cases also vary in how prior informed consent from local communities is asserted. In almost all the cases, access to traditional knowledge requires prior informed consent of the community from which it originated. Most cases also require prior informed consent of local communities for access to genetic resources. The bills under which the NCI–UNIP agreement operates differ over this issue. The Wagner bill allows local communities to directly deny access, while Bill No. 306 stipulates that local communities must request "the competent authority" to deny access to their lands. In this case, the power of the local community in deciding the fate of their resources is dependent on external authorities.

The Philippines and Fiji cases, in contrast, grant more autonomy to the local communities in deciding access. Access to genetic resources in the Philippines can only be granted "in accordance with the customary laws of the concerned community." In the USP–Verata agreement the Verata Council has complete autonomy over access to their genetic resources. In these last two cases, the local community has significant authority over their resources and may grant consent according to only their own wishes. In the Philippines the agreement goes so far as to recognize that local communities may have laws and customs that differ from the rest of the country and thus may influence whether they grant access or not.

What kind of information should be provided?

The USP–Verata agreement may serve as the model for maximizing participation of all parties. Their PIC agreement stipulates that Verata must be informed of all publications resulting from collections. Additionally, the agreement specifies for a written report in Fijian language on research activities to be presented to Verata every three months, and workshops are to be held every six months to discuss research progress. The Philippine agreements demand for all research drafts to be shared among all parties prior to publication. There are few of these provisions in other agreements. The INBio–Merck agreement does not specify any publication notice beside the responsibility of Merck to notify INBio of any anti-cancer activity detected. As a result, INBio may not get all the possible data on Costa Rica's biodiversity. The case in

Cameroon makes vague reference to research exchanges while calling for training and the provision of test results. The NCI–UNIP agreement requires the time of publication of research results to be jointly decided by both parties. Compared to the assurance of monetary exchange, which has prompted the regulatory response in the first place, research progress may not seem as important an aspect. Nonetheless, for all participants to make educated decisions about the future of their resource, this very issue may be critical.

DISTRIBUTION OF BENEFITS

The CBD's focus on the equitability of benefit sharing can be considered an attempt to address two main issues. In the first place, it aims to ensure that benefits derived from access to genetic resources translate into sustainable use and conservation as opposed to destructive exploitation of resources. Second, it aims to prevent the diversion of large monetary profits to non-local actors, as this practice has prevented local users and legal owners from benefiting fully from their natural and genetic resource endowment. This latter issue justifiably concerns many developing countries that have experienced biopiracy. It has, in some cases, generated misunderstanding and hostility towards foreign researchers. The establishment of "access rules" is expected to help mitigate these fears and result in access having a positive effect on all actors. Nonetheless, the achievement of both these goals depends to a great extent on the actual distribution of the benefits; it is then largely a question of "under what conditions compensation will be paid and... which social groups or institutions will have the right to determine those conditions."¹⁸⁴

Types of benefits

As can be seen from the cases presented in the previous chapter, myriad approaches to benefit sharing exist. This diversity results, in part, from the fact that a diversity of benefits can actually result from any agreement. All the agreements reviewed here recognize that benefits can exist in monetary and non-monetary form (see Table 4.1).¹⁸⁵

The distinction between monetary and non-monetary benefits may also be temporal: with the exception of up-front fees most royalty-derived benefits are expected to occur only in the long-term. This seems to be less clear to the general public and the governments of several megadiverse countries, which sometimes still have expectations of rapid and large monetary returns—effectively equating genetic resources with "green gold."¹⁸⁶ To avoid misunderstandings, some institutions have included in the text of their agreements explicit reference to the fact that monetary benefits may take decades to materialize, as in NCI's MoU. The African ICBG CRADA recognizes two types of benefits: "process" benefits, which result from the research and development phase, and "long-term" benefits, which arise from commercialization. Presenting the expected benefits in this way seems more realistic and could help parties understand the true temporal dimension of these agreements. An additional approach consists of differentiating commercial agreements from non-commercial agreements from the outset, as in the Philippine EO 247.

Table 4.1: Types of benefits.

Non-monetary	Monetary
• acknowledgment in publication • joint research and increased scientific capacity • participation in planning and decision-making • control over samples and research results • voucher specimens deposited in a national institution • co-ownership or sole ownership of intellectual property rights • free access to technology and products resulting from the agreement • protection of local existing applications of intellectual property rights • technology transfer (equipment and material donation) • training in bioprospecting methods, collection and preparation of samples, biodiversity monitoring, socioeconomic monitoring, and/or nursery and agronomic techniques (increased conservation capacity)	• bioprospecting fees • per-sample fees • percentage of research budget • percentage of royalties, • development of alternative income generating schemes • commitment to re-supply in source country, sample

A trend seems to be present in the agreements we have reviewed towards a lower representation of monetary benefits and a higher representation of non-monetary benefits, such as technology transfer and capacity building, in the first stages of an agreement. The INBio–Merck agreement, the CRA 98 in the Philippines, the African ICBG, the NCI–UNIP MoU, and the BioAndes application all strongly emphasize the training and capacity-building responsibilities of the technologically advanced and foreign parties to the source-country parties.

In addition, individuals, communities, companies, research and academic institutions, governments, and the international community are all potential beneficiaries. There is a hierarchical relationship among them so that the higher geographical and administrative levels include the subsequent lower ones. As a result of this hierarchy, benefits at a higher level, such as the international community or state government, could be perceived at each one of the levels below. As was discussed previously, this potential may or may not be realized depending on the type of relationship that exists between these different levels.

If, for instance, collection fees are reaped by the state but never reach the community that provides the actual resources, then the benefits would only be reaching some levels in this hierarchy. If the government uses these funds for conservation activities or capacity building, as in the Yellowstone–Diversa and INBio–Merck agreements, then the benefits are indirectly experienced at all levels. In the agreements that have taken place in Fiji, the short-term monetary benefits are directly channeled into the community and deposited in a trust fund. One way in which non-monetary benefits can reach the society at large is by increasing capacity in areas that are of critical importance to the country's economy, e.g., the BioAndes application to collaborate

in research on coffee pests, or UNIP's inclusion of tropical diseases as one of their research targets. Additionally, while non-profit organizations and NGOs may not contribute revenue through taxes, private companies such as BioAndes would certainly be contributing funds simply by operating in the country's territory. It may be harder for the environmental authorities to capture and invest the resulting funds into conservation if they initially go into the larger government budget. This might have been a concern of the Colombian MMA when evaluating the BioAndes applications.

Which of the potential beneficiaries are actually recognized as such in the agreements presented here? The agreements range from those that recognize only the national government through an agency, such as the Yellowstone–Diversa agreement, to those that include beneficiaries at all these levels, such as CRA 98 in the Philippines. Many others contain a combination of several beneficiaries: a government body (MINAE) and an NGO (INBio) in the INBio–Merck case. The agreements established by NCI with University of Yaounde in Cameroon (Letter of Collection) and with UNIP in Brazil only deal with research organizations. The complementary agreements that these organizations establish within the country, however, can extend benefits to additional levels. In all the cases reviewed, the proposed or passed access legislation contains provisions relating to each one of the levels mentioned, although the role of communities is more often one of providers of prior informed consent than one of direct negotiator and recipient of monetary benefits.

The recognition of different benefits and the beneficiaries in an agreement, however, does not necessarily provide the actual means by which distribution is to take place. We can see in the cases presented in Chapter III that benefit-sharing schemes dealing with monetary returns can be specifically determined, or, in other cases, be only vaguely required or explicitly postponed to later negotiations. In the case of the INBio–Merck and Yellowstone–Diversa agreements a mechanism for the distribution of monetary benefits is established from the outset, as can be seen by the assignment of royalty percentages to each party and their financial obligations with other stakeholders. An example is INBio's commitment to provide 50% of royalties to MINAE. The Philippines CRA 98 also establishes profit-sharing mechanisms from the outset.

The NCI–UNIP and NCI–University of Yaounde agreements, however, explicitly delay the negotiation of monetary benefit-sharing mechanisms to later stages, when a potential licensee is available. ARA 99 in the Philippines establishes that if potential commercial applications are discovered, monetary benefit-sharing arrangements are to be included in the development of a new agreement, this time a Commercial Research Agreement. Decision 391's access request primer includes no requirement of monetary offer specifications. Hence the first BioAndes application deferred detailed monetary arrangements to the contract negotiation phase that would ensue access approval. BioAndes experienced considerable difficulties trying to reach an agreement with the MMA regarding monetary benefit-sharing schemes. Discontent with BioAndes's proposed benefit-sharing schemes is consistently named among the MMA's reasons for rejecting these applications.

Delaying monetary benefit-sharing negotiations to later stages can also be a way to diffuse the hurdles imposed by regulation, and if the legislation is still being developed at the time of the application, it may allow the access applicant to negotiate those terms under a more clear

regulatory environment. For example, although guidelines for establishing these future agreements are provided, this route is the one followed by the SP Bill proposed in Brazil, while the bills proposed at the federal level vary in this respect. Because Decision 391 has not been regulated internally in Colombia, the MMA engaged in highly interpretative readings of this decision at the time of evaluating the BioAndes application.

Finally, it is interesting to examine which kinds of benefits have actually transpired in the course of the agreements presented here. No royalty or commercialization-derived monetary benefits have resulted from any of the agreements, except for the up-front payments realized in the Yellowstone–Diversa agreement, which are to be offset against future royalties. Monetary benefits have arisen out of bioprospecting fees and per-sample fees in the case of the agreements in the Philippines and Fiji. The largest benefits at this point in all of the agreements are undoubtedly those related to training and capacity building. In the case of the agreements in Cameroon, Fiji and Costa Rica, both the training of nationals and the transfer of new technology have taken place. Despite its recent establishment, the NCI–UNIP agreement in Brazil has already resulted in the training of a Brazilian scientist. The exact allocation of the funds that Yellowstone has received from Diversa is not known, but it is thought that they increased the Park's capacity to carry out research activities.

This tendency towards non-monetary benefits is partly a result of the recent establishment of these agreements and research projects but also of their strong focus on training and capacity building. It must be highlighted that this type of technology transfer is being easily achieved through private contracts, while it's been a contentious and somewhat stagnant issue within CBD discussions.

COMPLIANCE AND CONFLICT RESOLUTION

As discussed in Chapter II, the nature of genetic resources, uncertainty surrounding their use, the number of actors involved in access instances, and the reduced institutional and legal capacity of many source countries make the enforcement of legislation and agreements that regulate access to genetic resources difficult to ensure.¹⁸⁷ It is clear, however, that enacting measures to ensure compliance at levels of specific commercial contracts as well as national and international legislation and policy is crucial to the successful implementation of the new norms and procedures prescribed by the CBD.

At the level of the individual bioprospecting agreement, compliance depends upon the contractual environment, the particular relationship between the contracting parties, and the availability of an established legal system under which disputes may be resolved. In the larger arenas of national and international policy and legislation, compliance to the generalized norms and procedures informed by individual access agreements is determined by overall state capacity and the relative strengths of its collaborating institutions.

The cases we have described in Chapter III may be regarded as early experiments which test on the individual level the efficacy of the particular local, national, and/or international contractual environment. On the national level, they probe the efficacy of existing and proposed legislation to govern all bioprospecting arrangements in the present and future. The results of these

individual "experiments" may be instrumental in setting precedents that future agreements can be modeled upon and from which future legislation can be derived.

In taking a critical look at the case studies outlined in Chapter III, this analysis will address the following questions:

- Do the terms of the agreement/legislation encourage compliance?
- What mechanisms or provisions of the agreement/legislation deal with enforcement?
- How are conflicts resolved?

The most common way to encourage compliance involves communication between the parties. Compliance under the INBio–Merck agreement is addressed primarily by Article 2, which "requires that project directors realize informal consultations in person and by telephone regarding the management of the agreement and must regularly exchange the results of research and technical knowledge." The INBio–MINAE agreement also encourages compliance through mutual participation and frequent communication in collection, inventory, technical assistance, conservation, training, and other research activities. This type of arrangement is also working under the African ICBG agreement. Because both cases deal with comprehensive undertakings in bioprospecting and involve many individuals, there would conceivably be a greater likelihood of non-compliance if measures for collaboration, consultation and exchange were omitted. And yet because of the collective and intensely participatory nature of these agreements, the chance of defection and dispute may be reduced simply by these relationships being formed out of necessity and mutual dependence.

If the outcome of research is to succeed, collaborative effort and communication is essential, and if benefits are equitably distributed among stakeholders then defection is less likely. The inclusion of village chiefs, elders, and local healers as important partners under the ICBG arrangement, for example, has succeeded in creating an environment within which potential benefits are spread out among a diverse group of stakeholders, effectively increasing the incentive for cooperation. Compliance is a more complex issue, since regulating the actions of so many actors requires increased legal and institutional capacities that many of the countries involved have not yet succeeded in establishing.

In Brazil, the presence of a supervising national institution will provide an incentive for compliance in any agreement undertaken by a researcher. Under the SP Bill the responsibility of ensuring compliance with terms of the agreement between the state government and the collector is shared between the collector and a supervising national institution. The degree of cooperation between institutions may vary. This bill also provides for the monitoring of access activities to ensure adherence to the agreement, with the possibility of fines, confiscation of equipment and samples, and revocation of permits serving to encourage individuals to adhere to agreed terms. In the Philippines, the CRA 98 agreement requires that a performance bond be posted to ensure that activities are carried out in accordance with the provisions and terms of the agreement. If there are no violations, then the amount is returned when the collection is finished. This measure, albeit small, may serve to encourage compliance as well as conservation in the area of collection.

Under the Andean Pact, the problem of enforcement was named as one of the main concerns in the MMA decision to reject recent applications for bioprospecting in Colombia. Because of the

broad taxonomic and geographic scope of the requests, concerns about compliance were raised and it was determined that the limited institutional capacity of MMA was not sufficient to handle access requests that were not clearly defined in space and taxonomic scope. To this end, the application process now includes requirements calling for more detailed specifications when access to genetic resources is being sought. Nonetheless, whether the process itself encourages compliance has been debated and is not yet resolved, since few requests for either commercial or non-commercial activities have been submitted.

There is an apparent lack of attention given to designing systems of enforcement and dispute resolution under many agreements. National legislation as well as international treaties frequently fail to address the need to establish systems of monitoring and enforcement.¹⁸⁸ As a result, one of the greatest weaknesses of attempts to regulate access to genetic resources is the absence of institutional capacity designed to deal with issues related to compliance.

The conflict between traditional resource tenure and new provisions under recent laws enacted in Cameroon, Fiji, and Brazil, as well as under the Andean Pact, has created tension between government ministries and local communities, partly due the lack of institutional capacity to implement new provisions and resolve disputes.¹⁸⁹ In such cases, the establishment of ties to more developed legal systems through agreements between parties can smooth the transition and provide a model for the development of new systems of enforcement while regulating disputes, should they arise. Cameroon and Fiji are dependent upon the US and England, respectively, under agreements that allow disputes to be settled within established pathways. Most agreements in the cases studied include clauses that call for the parties to seek mutually agreed terms, relying upon effective communication as an instrument for the resolution of disputes.

Cases where enforcement mechanisms (audits, penalties: fines and sanctions and functional court systems) are in place, such as in the Philippines and under the INBio–Merck agreement, show that the agreements and the legislation can be upheld in a feasible manner. This is also true in the Yellowstone case, where the CRADA agreement states that any disagreements unresolved by the parties are to be handed over to the National Parks System, which is in turn supported by US law.

In summary, the enactment and enforcement of agreements through sanctions, penalties, and the threat of contract breach, modification, or suspension can enhance the credibility of the access regulation process, and increase the likelihood that these agreements will be honored.¹⁹⁰ In setting up a system to regulate disputes, access agreements have proven to be instrumental in the development of national access legislation, enabling communities and other stakeholders to validate their rights in the emerging global regime.¹⁹¹

CONSERVATION AND SUSTAINABLE USE

As stated in the objectives of the CBD, in order to conserve biodiversity, any use of its components, including genetic resources, must be sustainable. Sustainable use, as defined by the CBD, means using biodiversity in a way that does not cause its long-term decline, and thereby preserves its potential to meet the needs of future generations. Sustainable use can only occur

when the rights of different user groups are specified, when human needs are met, and when the losses in biodiversity and natural resources occur at rates within their capacity for renewal.¹⁹² To analyze the relationship between biodiversity conservation through sustainable use and regulated access to genetic resources, as described in the above cases, we have to answer if such activities meet the criteria of ecological and socioeconomic sustainability.¹⁹³ Hence, we must not restrict our analysis to the question of how negative impacts of such activities can be minimized. According to the goals of the CBD, it is crucial to explore how effective regulated access to genetic resources is in enhancing biodiversity conservation.

The criterion of *ecological sustainability* is directly related to conservation through the concepts of harvest and yield. At a species level, ecological sustainability is achieved when the harvest from the population does not exceed potential yield. At the ecosystem level, ecological sustainability is accomplished when harvest does not degrade the capacity of the ecosystem to sustain itself.¹⁹⁴

Our analysis, however, is limited because the recent history of the cases preempts discerning any notable effects of bioprospecting activities on biodiversity. Thus it would be impossible to draw solid conclusions as to the sustainability of these activities. Therefore our discussion is largely based on the possible effects of the activities described in the agreements and legislation rather than on their practical application.

The overall language of the agreements and legislation requires the parties to adhere to the international and state legislation dealing with biodiversity conservation. All agreements and legislation demand that the collection of genetic resources must strictly adhere to established protocols. The principal collectors and co-collectors must harvest specified species only in the quantities stipulated in the agreement and only in designated areas. In all the reviewed cases, except BioAndes, the potential negative impact of bioprospecting activities is considered by the Parties to the agreements to be minimal, despite evidence to the contrary from other instances of access to bioprospecting.¹⁹⁵ In the Yellowstone and Philippine agreements, quantities identified for extraction are considered to be too minute to be a cause for concern. This presupposes that the Parties to the agreements know beforehand what levels of harvest are sustainable. Such knowledge, however, is lacking in those instances when new or poorly studied species become a target of bioprospecting. In Cameroon, leaf litter rather than live leaf material is collected presumably alleviating any concerns over the ecological sustainability of such activity. It is unclear, however, what effect leaf litter removal has on the overall resilience of the ecosystem.

Post-collection monitoring is crucial to assess the impacts of bioprospecting on biodiversity. The agreements, however, place greater emphasis on monitoring during the collection phase, while post-collection monitoring is given a lower priority. Agencies and parties responsible for monitoring of bioprospecting activities are identified in all the cases, and procedures and financial responsibilities are described in detail. Nonetheless, specific protocols and financing arrangements for post-collection monitoring are not outlined. This is also complicated by the fact that the parties required to monitor these activities often lack adequate funds and infrastructure to implement their mandate.

All cases stress the importance of improving conservation efforts through resource and landscape management, education, coordinated research, and rural development. In Cameroon and Nigeria, the commercial value of *Ancistrocladus korupensis* has encouraged the development of trans-boundary initiatives in order to conserve the species. In Costa Rica, a payment of \$100,000 provided direct support to the country's conservation efforts, while the project also supported activities aimed at educating the public about the value of biodiversity. However, given the \$1 billion price tag for ten years worth of maintenance of Costa Rica's national park system, the lump-sum paid to date may be a "drop in the bucket."¹⁹⁶ Both Philippine agreements emphasize the importance of biodiversity inventories for proper management and conservation of ecosystems. Seemingly the opposite is true in the Yellowstone agreement which, according to the Park's officials, has no effect on conservation efforts. Nevertheless, several stakeholders in this case have expressed concern about the negative effects of "commercializing" conservation.

Finally, one major element seems to be lacking from most of the new access legislation: evaluation. Have the benefits derived had any impact on the area from which resources are obtained? Have any major unintended social or environmental impacts resulted from the new regime? Provisions for broad evaluation of this kind are not established in any of the regulatory measures examined.

If bioprospecting is to become a viable way of financing biodiversity conservation,¹⁹⁷ its socioeconomic sustainability is as important as ecological sustainability. The socioeconomic sustainability criterion is defined as the capacity to meet the economic needs and aspirations of the human users over an extended period of time.¹⁹⁸ We can only indirectly infer socioeconomic sustainability from the described cases. In addition to being very recent, the agreements are also of short duration, making any extrapolation highly speculative.

CHAPTER V. CONCLUSIONS AND RECOMMENDATIONS

At the outset of this project our goal was to examine and critically evaluate the efficacy of seven examples of AGR agreements in achieving the goals of the CBD. As a result of our analysis we have arrived at a number of conclusions, and these have led us to several recommendations pertinent to policy and decision-makers involved in the AGR regulation process.

1. During policy development existing regional institutions and cooperation frameworks have provided operational support. One way to make regulatory efforts more expeditious and cost-effective is by using a regional cooperation framework to coordinate legislation development. Similarly, an academic or NGO cooperation framework may assist in coordinating bioprospecting efforts, as in the case of the African ICBG. The OAU framework draft legislation encourages the type of in-country discussion and legislation development that is unlikely to be initiated on a country-by-country basis. It can also prevent the duplication of efforts and allow for the coordination of regulatory regimes among neighbors, as in the case of Decision 391 of the Andean Pact.

But working in a regional framework has its disadvantages. The realities of implementing a regional regulatory regime shift point to a more complicated scenario. For example, there is still inconsistency in the way in which Decision 391 is being implemented within the Andean Pact countries.¹⁹⁹ In addition, countries must be aware that regional legislation will be more difficult to change in the future.

Recommendation: We recommend that nations which currently do not have the capacity to develop regulatory regimes take advantage of existing regional institutions that can aid them in the process.

2. New AGR regimes lack procedures to assess the achievement of CBD objectives.

Although it is still too early to evaluate the conservation and sustainability of the AGR regimes examined, such evaluation is essential. The endurance of a new legal regime should be contingent on the evaluation of its effects on the source country at a broad level, including the possibility of unintended social and environmental consequences. For example, improved socioeconomic conditions in the area covered by an agreement could lead to the increase in human immigration and increased pressure on biological resources.²⁰⁰ Agreements often require assessment of compliance with their own terms (e.g., the INBio–Merck agreement), but they lack specific provisions that mandate post-agreement assessment of their impacts on sustainable use, conservation, and equitable distribution of benefits in the long term.

Recommendation: Independent, multidisciplinary evaluation of the success of the access policy in achieving CBD objectives must be incorporated into AGR regimes. It would be pertinent to consider this issue during negotiation of agreements so that training of in-country persons in this area or the hiring of consultants to perform this task can be arranged. In those agreements that must be periodically renewed, the renewal process could require an evaluation report.

3. Minimizing the number of parties facilitates the establishment of agreements, but may ultimately lead to failure by excluding the interests of relevant stakeholders. Most of the

cases involve access to publicly owned lands, thereby eliminating the need to consult with private parties or indigenous groups prior to gaining access to genetic resources. The BioAndes application is the most obvious example of a party trying to avoid the complexities of private property rights; this application stipulates that BioAndes would avoid collecting genetic material in protected areas where property rights are contested by local communities and/or individuals.

Participation of all stakeholders is essential to effectively implement regulations and achieve the long term goals of the CBD; failure to recognize and involve stakeholders during the formulation of agreements may jeopardize their successful implementation. For example, the successfully negotiated Yellowstone–Diversa agreement establishes that Diversa is only required to gain acquiescence from the US Government, but a lawsuit has been brought against the agreement by previously unidentified stakeholders. Conversely, in the Brazilian case Senator Marina Silva, author of Bill No. 306, made a concerted effort to circulate drafts of the bill among a variety of stakeholders and to incorporate their issues into the bill. This effort was not considered adequate by some legislators, and the introduction of a revised bill by Representative Jaques Wagner contains alterations that address the explicit concerns regarding the rights and representation of indigenous peoples and traditional communities.

Recommendation: During the policy development process the entities directly involved in policy formulation should attempt to identify and seek the participation of other stakeholders.

4. The ability of regulated AGR to expand conservation efforts is limited because most agreements take place on land where conservation is already underway. In an effort to facilitate the establishment of agreements and maximize diversity of resources they have access to, bioprospectors seek areas where (1) property rights are clearly established, (2) a minimal number of parties are involved in negotiations, and (3) biodiversity is high. Frequently, this leads them to target state-owned national parks and other protected areas. This is illustrated by the Yellowstone–Diversa agreement, the BioAndes applications, and the NCI–UNIP agreement in Brazil, all of which exclusively involve state protected areas. However, this strategy fails to augment current conservation efforts and therefore limits the impact that access regulations can have in transforming land-use practices.

Recommendation: Bioprospecting initiatives based outside state-protected areas should be encouraged. Examples of places that satisfy the requirements outlined above but are not currently targeted for conservation include reservations managed by indigenous peoples and undeveloped, privately owned land.

5. There is a contradiction between disclosure of terms in access agreements for stakeholder involvement and right to confidentiality of parties in the transaction. In the case of the Yellowstone–Diversa agreement, the terms of actual royalty payments to the park are confidential. Whereas this is common business practice, it must be recognized that Yellowstone National Park is owned by the US public. Arguably, the public has the right to know the details of a financial arrangement which concerns the transfer of genetic information obtained through prospecting on public land. Although it may not be feasible to address this issue in the short term, we believe it is important to highlight the difficulties associated with the current state of

affairs so as to stimulate the discussion of this topic. The fact that a large portion of current worldwide bioprospecting is done in public lands adds relevance to this issue.

6. There may be few incentives arising from access to genetic resources to preserve resources that local communities do not legally own. Governments have asserted their sovereign rights over genetic resources, but in many cases the land remains under traditional tenure while the property rights system grants ownership of all genetic resources therein to the state. Usually, only resource owners and users participate in the negotiation of agreements and only the resource owner receives the benefits. The burden of sustainable use and conservation, however, rests on the communities. It is unlikely that sustainable land-use practices will be embraced by local communities if AGR policy does not provide them with ownership of the genetic resources they tend and benefits derived therefrom.

Recommendation: National policy should address the conflict between traditional land tenure and legal property rights of genetic resources, so as to match conservation obligations with the benefit-sharing rights implicit in AGR policy.

7. AGR regulations may raise the costs of negotiating access and create a disincentive to use biodiversity. Pursuant to the goals of the CBD, AGR policy aims to both regulate and facilitate access. Clearly defined regulatory protocols can facilitate access by informing potential users of source-country requirements prior to initiating the application process, but only if the regulations are not prohibitively restrictive. Extreme regulation raises the overall cost (monetary and otherwise) of using genetic resources—many of which were easily accessible until recently—and may prevent genetic resources from being used. This problem affects national, international, commercial, and non-commercial ventures alike. For example, every Colombian biologist is required to obtain a permit before collecting specimens, and strict application of Decision 391 would require the MMA to scrutinize their applications in the same way as those of multinational pharmaceutical companies. Given its much reduced operating budget, it is likely that the MMA would be unable to contend with so many applications, and basic biological science within Colombia would be seriously hampered. Because the goals of conservation and distribution of benefits can only be achieved if genetic resources are accessed, it is imperative that policy makers reconcile the potentially conflicting goals of regulating and facilitating access to genetic resources.

New AGR regulations may further increase the cost of negotiating access by nullifying pre-existing agreements or requiring renegotiation of terms. Consequently, the often lengthy process of developing regulations creates a "window of uncertainty" during which parties are reluctant to apply for access, and source-country authorities inclined to reject or postpone them.

Based on the cases we examined, it is difficult to determine the extent to which the balance between regulating and facilitating access has been achieved. The complexity of the issue is illustrated by the failed BioAndes applications to gain access in Colombia. In the Philippines only two of 37 applications have been approved, but it must be noted that these two successful cases will most likely serve as templates for future applications, thereby improving the chance of their approval.

One way in which parties have ensured compliance with changing national regulations while reducing the cost of negotiation is by using a system of two complementary agreements, one between the foreign bioprospector and a source-country organization, and the other between this organization and the local authorities (see Table 5.1). Because of the overlap in the agreements, this system ensures that the interests of all parties are accounted for while reducing the number of parties involved in each set of negotiations. This system prevents the foreign party from having to negotiate the specific local aspects of the agreement—a situation which could be extremely difficult—and makes the international agreement more resilient to changes in the regulatory environment of the source country. For example, by participating in the Special Mixed Subcommission that developed Costa Rica's Biodiversity Law, INBio was able to ensure that the new legislation did not jeopardize the agreement with Merck.

In addition, some agreements and legislation postpone the negotiation of detailed benefit-sharing schemes to later stages, effectively diffusing the costs of negotiation over time and avoiding uncertainty in legal requirements and rights if legislation is still being developed. NCI's MoU with UNIP in Brazil, for example, requires parties to undertake detailed benefit-sharing negotiations only when the prospects of monetary benefits arise, and the agreement has persisted in a highly dynamic regulatory environment. It appears that the BioAndes application was aiming to achieve just that as well.

Table 5.1: Parties to complementary AGR agreements.

Country	Foreign party	Source-country organization	Source-country authority
Costa Rica	Merck	INBio	MINAE
Brazil	NCI	UNIP	SMA
Colombia	Andes Pharmaceutical	BioAndes	MMA
Fiji	SIDR	USP	Verata Council

8. An additional hindrance to AGR is the use of the same standards in commercial and non-commercial access requests. Since commercial access deals with high monetary stakes, access regulations have become increasingly restrictive and commerce-oriented. Hence, as has been denounced by the scientific community,²⁰¹ a cumbersome, unnecessarily strict application process is imposed on what is considered basic, not-for-profit research. This basic scientific investigation significantly increases the value of genetic resources through discovery and increased understanding. It is required to understand natural processes essential to conservation, and it almost invariably precedes commercially oriented research. Failure to explicitly recognize the fundamental differences between commercial and non-commercial research in AGR policy may cause essential research to grind to a halt, which would result in failure to meet the goals of the CBD. For instance, as discussed above, full enforcement of Decision 391 in Colombia would render all current scientific collection projects illegal—including those performed by national universities, Colombian state agencies, and other institutions, none of which have undergone the application process prescribed by Decision 391. However, it is often impossible for source-country authorities to distinguish between commercial and non-commercial projects. Since samples can be used repeatedly and for multiple purposes, and because the ultimate results of any scientific investigation are unpredictable, basic scientific research has the potential to lead to commercial discoveries.

Recommendation: Since there is no objective criterion to draw the boundaries between non-commercial and commercial research, and to avoid discouraging research that may benefit biodiversity conservation, we recommend that countries provide a "two-track" application process, where any access applicant would be able to choose between either one of the two "tracks" according to their priorities.

- Type I agreement: A simple research permit in which researchers forgo the right to any future monetary benefits arising from commercialization and IPRs, which belong to the resource owners.
- Type II agreement: A more complex contractual agreement which would involve negotiations of IPRs and both monetary and non-monetary benefits with the resource owners, as defined in the specific national and local context.

The advantage of this system is that the users themselves define their intentions, avoiding the need to infer them from the project description or other criteria. Large numbers of stakeholders must be consulted and detailed terms of benefit sharing negotiated only when IPR and financial benefits are an issue. By stating in a legally binding agreement that they do not claim any ownership rights over future commercial discoveries and resulting benefits, parties interested only in basic research could avoid more costly negotiations. Somewhat counter-intuitively, the Type I agreement represents one of the most restrictive agreements possible, in which users are only granted ownership of the sample itself and permission to study the material they collect.

Monitoring of Type I agreements is a high priority for source countries, but no more so than in Type II agreements. In any international AGR agreement, the ability of the source-country agencies to monitor the activities of foreign users and ensure compliance is limited. As part of their role as CBD signatories, it would be appropriate for countries to require disclosure of sample source, the terms under which it was obtained, and other relevant data in applications for patents and import permits.

It must be noted that the Type I agreement would not preclude the need for fair compensation—either monetary or in-kind—to the local community, source country, or source-country institutions, as provided by their regulations. It would also not preclude the commercialization of the discoveries by the resource owners. Furthermore, it would not prevent users from entering into a more complex Type II agreement equipped with benefit-sharing provisions in the future.

Type II agreements could be structured as a framework agreement containing a variable number of clauses that come into effect as they become applicable. The Provisional Bioprospecting Contract included in the Brazilian Federal Bill No. 306 is an example of what the first step in the Type II agreements could be like. Although the uses permitted in the Type I agreement could be viewed as the first step in the establishment of the Type II agreement, treating them as completely separate agreements underscores the fundamental differences between commercial and non-commercial ventures and encourages the basic biological research that is essential to achieving the goals of the CBD by preventing over-regulation.

9. The main benefits to be obtained from access agreements will most likely be non-monetary, i.e., capacity building, technology transfer, joint research, and training. A common argument in AGR discussion, as it relates to the goals of the CBD, is that substantial

cash profits that would enhance conservation can be generated from bioprospecting.²⁰² Nevertheless, the economic value of bioprospecting for conservation is still subject to debate.²⁰³ Some economists suggest that for some genetic resources the value could be large enough to support market-based conservation of biodiversity,²⁰⁴ whereas others argue that the value is going to be extremely small, creating no conservation incentives in the face of habitat conversion.²⁰⁵

At the time of this analysis, no active compound has been advanced into the commercialization phase; as of yet, no royalty or commercialization-derived monetary benefits have resulted from any of the agreements. The odds of finding a new drug from botanical samples are still very low (from 1 in 80,000 to 1 in 250,000 plant samples).²⁰⁶ Considering the investment that drug development requires, only companies with large research budgets may expect to reap the monetary benefits from commercialization. In fact, some pharmaceutical companies, such as Shaman, have recently cut back on their bioprospecting activities because costs proved higher than expected.²⁰⁷

Many of the access agreements reviewed here—those in the Philippines, the SIDR–USP agreement in Fiji, INBio–Merck, the African ICBG, the NCI–University of Yaounde Letter of Collection, and the NCI–UNIP MoU—as well as the BioAndes application—strongly emphasize the training and capacity-building responsibilities of the foreign parties. Therefore training and capacity building, as emphasized by these agreements, are likely to be much more important than monetary benefits in the short and long term. They may also address conservation goals in a shorter term.

Recommendations: When establishing agreements all parties should acknowledge that benefits obtained from access will for the most part be non-monetary, and that monetary benefits may be elusive. Education of resource owners should emphasize that long-term royalty benefits are unlikely.

CONCLUDING REMARKS

In conclusion, we may ask: Are these agreements successfully achieving the three goals of the CBD? As was mentioned in Chapter IV, the youth of the studied AGR regimes prevents us from assessing their performance in relation to sustainable use and conservation. Some weaknesses, however, such as those noted in the areas of evaluation and access application protocols, have been identified and can be incorporated into current policy discussions. Given recent developments in AGR regimes, we believe that perceptions of the monetary value of genetic resources will become more adjusted to reality.

A better way to gauge the success of AGR agreements may be to rephrase the above question as follows: Do these agreements provide ways to overcome the obstacles to regulating access and achieving the goals of the CBD? As can be expected, the degree to which they accomplished this varies among the cases examined and the types of obstacles. Some of the obstacles outlined in the preceding chapters seem to be very difficult to overcome, while others are being reduced.

Those obstacles arising out of the nature of genetic resources—such as the difficulties in dealing

with genetic resources as information—are more difficult to overcome, but can be incorporated when designing and evaluating regulations or agreements. The incongruence between the political framework and the geographical pattern of ecosystem distribution may be addressed more effectively in those cases where regional initiatives are under way.

The conflicts surrounding property rights have not been addressed successfully, essential as this is to the implementation of benefit-sharing mechanisms. As was discussed above, the complications that arise out of the new, post-CBD genetic resource ownership regime are still relatively unexplored, and they must be overlaid on centuries-old land rights strife.

As illustrated by the Yellowstone–Diversa agreement and the differences between the alternative federal bills in Brazil, reconciling the diverging interests of stakeholders remains a challenge in many instances. But in others, such as the agreements in Fiji, the involvement of a variety of stakeholders seems to have resulted in a satisfactory arrangement for all involved.

In the case of *ex situ* collections, the practicality and rationale of repatriating museum collections and herbaria are severely questioned by the scientific community. Scientists argue that the disintegration of large collections would hinder research activities and that most developing nations would find the cost of maintaining large scientific collections to be prohibitively high.

The obstacles arising out of low institutional, legal, and scientific capacity are most rapidly affected by AGR agreements and regulations. Examples abound in our case studies of instances wherein the development of a private contract greatly improved the ability of a country to handle requests for access. As those countries currently developing legislation implement it, and if they recognize the consequences brought about by over-regulation, it is expected that access procedures will become clearer and more effective for both national and foreign interests.

We hope that the recommendations we provide here will be considered by policy makers, for we feel that they highlight areas that need to be addressed if countries are to achieve the objectives of the CBD.

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⁸⁶ The standard Collaboration Agreement stipulates a five-year period of confidentiality, but the Merck agreement provides for seven years of confidentiality.

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⁹¹ Specifics of how access is granted are established in Chapter V, *Access to Genetic and Biochemical Elements and the Protection of Associated Knowledge*.

⁹² See also Article 65, discussed below under Prior Informed Consent.

⁹³ Excluding endangered species. Both INBio and Merck prohibit the collection of endangered species, relying on local experts and CITES regulations, respectively.

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⁹⁹ A version amended by Senator Omar Diaz of National Bill No. 306 has been approved by the Senate Committees on Social Affairs and Education and is presently in debate in the House.

The bill "Provides for the access to genetic resources and their derived products and makes other provision."

¹⁰⁰ Precise differences in the text of the Wagner bill and the Senate Bill No. 306 include the following: (a) The title of the Wagner bill specifically mentions the protection of traditional knowledge whereas the Bill 306 does not; (b) The Wagner bill refers to Law 7.347/85, which allows for public civil actions, and to Article 232 of the Federal Constitution which confers the right of indigenous peoples to represent themselves or their organizations in a court of law; (c) The Wagner bill affords indigenous peoples and traditional communities the right to deny access to their resources rather than relying on the competent authority to do so; and (d) Article 2 recognizes additional indigenous property rights by referring to the terms of Article 231 of the Federal Constitution.

¹⁰¹ Letter to the President. E.M. No. 8. 19 August 1998.

- ¹⁰² The protocol for access request and contract development is detailed in both these bills in Title IV, Chapter I, Section I - The Petition and the Project of Access and Section II - The Contract of Access.
- ¹⁰³ Lyrio Silva, Fernando. Legislative consultant, Federal Senate of Brazil. Personal interview. 8 March 1999.
- ¹⁰⁴ Benefit sharing is dealt with in Articles 2 in general, 35 and 36 for the state, and 44 and 46 for indigenous and traditional communities.
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- ¹⁰⁶ Amaral de Azevedo, Cristina. PROBIO, Brazil. Electronic mail correspondence. 30 March 1999.
- ¹⁰⁷ Minority populations known as "quilombos" (descendants of African slaves) usually inhabit areas inside protected areas. Amaral de Azevedo, Cristina. PROBIO, Brazil. Personal communication. 8 March 1999.
- ¹⁰⁸ Arcanjo, Eugenio. Legislative consultant, Federal Senate of Brazil. Telephone interview. 29 April 1999. Arcanjo reports the issue of ownership of these newly valued resources had been contentious throughout the drafting of the Senate bills, but when the GIARG group presented the constitutional amendment, much of the argument among different stakeholders ceased.
- ¹⁰⁹ There is an initiative by PROBIO to regulate the legal status for territorial occupation by traditional communities.
- ¹¹⁰ Organizations from the following countries are also collaborating with NCI under an MoU: Costa Rica, Mexico, Panama, Bangladesh, China, Korea, Pakistan, New Zealand, South Africa, and Zimbabwe. Cragg, Gordon. Telephone interview. 30 March 1999.
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 MMA. 1998 *Resolución número 1146 por la cual se resuelve el recurso de reposición contra la Resolución 984 del 21 de octubre de 1998, que denegó la solicitud presentada por la sociedad BioAndes de Colombia S.A.*
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MMA. 1998 *Resolución número 0984 por la cual se deniega la solicitud de acceso a los recursos genéticos, presentada por la Sociedad BioAndes de Colombia S.A.*

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Pardo, María del Pilar. Researcher at the Policy and Legislation Program at IVH, electronic mail communication 26 February 1999.

Pombo, Diana. Advisor to the Vice-Minister of the Environment, Colombia. Telephone interview, 29 March 1999.

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Yunis Mebarak, José. Mail correspondence. 9 April 1999.

¹¹⁸ Bryant, D., D. Nielsen & L. Tangle. 1997. *The last frontier forests ecosystems and economies on the edge*. Washington DC: World Resources Institute.

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¹¹⁹ *Instituto de Fomento Industrial*, a government-funded organization for the improvement of industrial alternatives in economic growth.

¹²⁰ This program is presided over by the Ministry of Development and advised by COLCIENCIAS, the Colombian National Science Foundation.

¹²¹ Muñoz, Armando. Biotec Laboratory employee. Email communication. 7 April 1999.

¹²² At least three of them are members of *Grupo Semillas*, a Colombian environmentalist NGO.

¹²³ The contained appraisal was a "relative analysis of the quality, results, economic and financial aspects and the company's experience, among others."

¹²⁴ The passage submitted by BioAndes reads "In the collection stage, BioAndes will collect biological resources. In the extraction stage these biological resources will be converted into derivatives (alkaloids, proteins, peptides and other molecules). In the bioassay stage these molecules will be screened for cancer specific activity. Therefore one may say that BioAndes starts with the biological resource and ends with the genetic resource."

¹²⁵ Flórez, M & S. Pimiento Chamorro. 1998. Colombia, pp. 59–66. In *Measures to control access and promote benefit sharing: A selection of case studies*, N. Vallejo and D. Stone (eds.). Gland, Switzerland: WWF.

¹²⁶ MMA. 1997. *Ordenamiento Territorial* [On-line] Available: <http://www.minambiente.gov.co/o-territorial/o-territorial.htm>

¹²⁷ Acevedo, Claudia. Former director of Munchique National Natural Park. Personal communication. January 1995.

¹²⁸ Dávalos, L.M. 1999. The San Lucas mountain range in Colombia: how much conservation is owed to the violence? *In preparation*.

¹²⁹ Palacio, Juan Diego. Head of the Biotechnology Laboratory, IVH. Electronic mail communication. 16 February 1999.

¹³⁰ Flórez, M & S. Pimiento Chamorro. 1998. Colombia, pp. 59–66. In *Measures to control access and promote benefit sharing: A selection of case studies*, N. Vallejo & D. Stone (eds.). Gland, Switzerland: WWF.

¹³¹ Palacio, Juan Diego. Head of the Biotechnology Laboratory, IVH. Electronic mail communication. 16 February 1999.

¹³² *El Colombiano*. 26 March 1998. *Acceso a recursos genéticos de Colombia, a un paso* Medellín.

¹³³ Asebey, Edgar J. Andes Pharmaceuticals CEO. Telephone interview. 26 March 1999.

Collar, Nigel. President BirdLife International. Personal communication. 3 November 1998.

¹³⁴ *El Tiempo*. 7 April 1999. *Minhacienda reta a Serpa a debate público*.

¹³⁵ Ruiz, Manuel. Telephone interview. 7 April 1999.

¹³⁶ For instance: if CITES listings are not sufficient to determine whether an organism is threatened or not, then which technical criterion can be used? Which institutions would undertake such an assessment? Is random collection impossible to monitor as the MMA claims? Is random collection absolutely necessary for this kind of project to succeed as BioAndes claims? Does the State need to participate in all possible patents, or are royalty schemes

enough? Since the MMA decided that the monetary offer BioAndes made in the second application was too low to initiate negotiations, how much do they require? Moreover, who decides the economic worth of these resources?

¹³⁷ The information here presented was compiled from the following sources:

Egbe, E. S. 1998. *Study on National Legislation Relative to Access to Genetic Resources and Benefit Sharing*. Report prepared for WWF-CPO. Consultancy Contract Reference No. 9Z0692.10. Draft version.

Iwu, M. & Laird, S. 1998. The International Cooperative Biodiversity Group. *Drug Development and Biodiversity Conservation in Africa: Case Study of a Benefit-Sharing Plan*. Submitted in response to the Call for Benefit Sharing Case Studies by the Secretariat of the Convention on Biological Diversity. [On-line]. Available:

http://www.biodiv.org/chm/techno/casestudies_pdf/ICBG-Africa.pdf

Laird, Sarah. Personal interview. 5 March 1999.

Ministry of the Environment and Forestry (MINEF), Republic of Cameroon. 1994. *Law No. 94/01 of 20 January 1994 to Lay Down Forestry, Wildlife and Fisheries Regulations*. Published by the MINEF Communication Unit.

Republic of Cameroon. 1996. *Law No. 96/12 of 5 August 1996, Portant Loi-Cadre Relative à la Gestion de l'Environnement*.

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¹³⁸ Iwu, M. & Laird, S. 1998. The International Cooperative Biodiversity Group. *Drug development and biodiversity conservation in Africa: case study of a benefit-sharing plan*. Submitted in response to the Call for Benefit Sharing Case Studies by the Secretariat of the Convention on Biological Diversity. [On-line]. Available:

http://www.biodiv.org/chm/techno/casestudies_pdf/ICBG-Africa.pdf

¹³⁹ Mays, T. D., K. Duffy-Mazan, G. Cragg, & M. Boyd. 1997. A paradigm for the equitable sharing of benefits resulting from biodiversity research and development. pp. 267–80. In *Biodiversity and human health*, F. Grifo & J. Rosenthal, (eds.) Washington, DC: Island Press.

¹⁴⁰ Stone, D. & Vallejo, N. (eds.). 1998. *Measures to control access and promote benefit sharing: A selection of case studies*, Gland, Switzerland: WWF International.

¹⁴¹ Egbe, E. S. 1998. *Study on national legislation relative to access to genetic resources and benefit sharing*. Report prepared for WWF-CPO. Consultancy Contract Reference No. 9Z0692.10. Draft version.

¹⁴² The information for this case was derived primarily from the following sources:

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¹⁴³ The information here presented was compiled from the following sources:

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University of Utah. 1999. *The Ireland Research Group*. Available: <http://ocean.pharm.utah.edu/>

University of Utah. 1999. *Description*. Available: <http://www.admin.utah.edu/president/docs/mission.html>

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¹⁴⁵ As a member agency of IACBGR, DA must:

- (a) Create a multi-disciplinary committee that will evaluate the proposals on bioprospecting agriculture and fishery concerns and recommend further evaluation to the IACBGR;
- (b) Through the Secretary or his authorized representative, sign/approve Research Agreements concerning prospecting of agricultural and fishery biological and genetic resources;
- (c) Through the Bureau of Agricultural Research (BAR), monitor and evaluate the implementation of the Research Agreements ; and,
- (d) Formulate policies and issue permits relative to the acquisition, importation and exportation of agricultural and fishery commodities on biological prospecting and genetic resources not covered in the DAO 96-20.

¹⁴⁶ "In its role as research university, the University of Utah fosters the discovery and humane use of knowledge and artistic creation in all areas of academic, professional, and clinical study. In both basic and applied research, the University measures achievement against national and international standards. "

"The Ireland Research Group is a marine natural products drug discovery program in the Department of Medicinal Chemistry at the University of Utah. It looks for new chemicals in marine organisms that could be used as drugs to treat diseases. Cancer is the main."

¹⁴⁷ The University was established on 18 June 1908, by Act 1870, to give advanced instruction in literature, philosophy, the sciences, and arts, and professional and technical training to every qualified student, irrespective of age, sex, nationality, religious belief, or political affiliation. It is the first and premier state university of the country that has become a comprehensive national university system with six autonomous universities—UP Diliman, UP Los Baños, UP Manila, UP Visayas, UP Open University and UP Mindanao—operating in 11 campuses nationwide. The University provides direct community service to many undeserved areas in the country through more than a hundred extension programs.

¹⁴⁸ According to DAO 96-20: Section 10.3.5, as a member agency of IACBGR, the DENR must:

- (a) Assist in the review and evaluation of research proposals pertaining to wildlife resources which management falls within its jurisdiction;
- (b) Through the Secretary or his authorized representative, sign/approve Research Agreements relative to prospecting of wildlife resources which management falls within its area of jurisdiction;
- (c) Monitor and evaluate the implementation of the Research Agreements.
- (d) Act as Chairman of the Technical Secretariat (TS) of the IACBGR and lead in the performance of the functions of the TS; and,
- (e) Serve as the central depository of all documents relative to bioprospecting.

¹⁴⁹ According to DAO 96-20: Section 10.3.3, as a member agency of IACBGR, DOST must:

- (a) Assist in the identification, assessment and involvement of local and international institutions that may wish to be part of bioprospecting activities;
- (b) Through the Secretary or his authorized representative, sign/approve Research Agreements concerning germplasm collection, documentation, conservation, evaluation and utilization, and related bioprospecting activities;
- (c) Monitor and evaluate the implementation of the Research Agreements the agency entered into; and,
- (d) In collaboration with other governmental agencies and institutions, be responsible in setting directions and formulating policies on plant aquatic and marine genetic resources.

¹⁵⁰ According to DAO 96-20: Section 10.3, as a member agency of IACBGR, DOH must:

- (a) Through the Traditional Medicine Unit (TMU), assist in the review and evaluation of research proposals in the areas of pharmaceutical/medicinal research and development, including the utilization of extracts, products and by-products and derivatives for commercial and academic purposes;
- (b) Through the TMU, monitor and evaluate the implementation of the Research Agreements the agency entered into;
- (c) Through the TMU, coordinate all research activities related to medicinal plants and act as a screening body to prevent duplication of proposals by keeping a database on these proposals; and,

(d) Through the TMU, enforce the protection of our medicinal plants from unauthorized exploitation by channeling appropriate action to the appropriate government agencies.

¹⁵¹ "Indigenous Cultural Communities/Indigenous Peoples (ICCs/IPs)—A group identified by self-ascription and ascription by others, who have continuously lived as organized community communally bounded and defined territory, and who have, under claims of ownership since time immemorial, occupied, possessed and utilized such territories, sharing common bonds of language, customs, traditions and other distinctive cultural traits, or who have, through resistance to political, social and cultural inroads of colonization, non-indigenous religions and cultures, became historically differentiated from the majority of Filipinos." (The Indigenous People's Rights Act of 1997. Chapter II. Section 3(h).)

¹⁵² "Ancestral Domains—All areas generally belonging to ICCs/IPs comprising lands, inland waters, coastal areas, and natural resources therein, held under a claim of ownership, occupied or possessed by ICCs/IPs, by themselves or through their ancestors, communally or individually since time immemorial, continuously to the present except when interrupted by war, or displacement by force, deceit, stealth or as a consequence of government projects or any other voluntary dealings entered into by government and private individuals/corporations, and which are necessary to ensure their economic, social and cultural welfare. It shall include ancestral lands, forests, pasture, residential, agricultural, and other lands individually owned whether alienable and disposable or otherwise, hunting grounds, burial grounds, worship areas, bodies of water, mineral and other natural resources, and lands which may no longer be exclusively occupied by ICCs/IPs but from which they traditionally had access for their subsistence and traditional activities, particularly the home ranges of ICCs/IPs who are still nomadic and/or shifting cultivators." (The Indigenous People's Rights Act of 1997. Chapter II. Section 3(a).)

"Rights to Ancestral Domains—The rights of ownership and possession of ICCs/IPs to their ancestral domains shall be recognized and protected. Such rights shall include:

(a) *Right of Ownership*—The right to claim ownership over lands, bodies of water traditionally and actually occupied by ICCs/IPs, sacred places, traditional hunting and fishing grounds, and all improvements made by them at any time within the domains;

(b) *Right to Develop Lands and Natural Resources*.—The right to develop, control and use lands and territories traditionally occupied, owned, or used; to manage and conserve natural resources within the territories and uphold the responsibilities for future generations; to benefit and share the profits from allocation and utilization of the natural resources found therein; the right to negotiate the terms and conditions for the exploration of natural resources in the areas for the purpose of ensuring ecological, protection and the conservation measures, pursuant to national and customary laws; the right to an informed and intelligent participation in the formulation and implementation of any project, government or private, that will affect or impact upon the ancestral domain and to receive just and fair compensation for any damages which they may sustain as a result of the project; and the right to effective measures by the government to prevent any interference with, alienation and encroachment upon these rights" (The Indigenous People's Rights Act of 1997. Chapter III. Section 7.)

¹⁵³ "The State shall respect, recognize and protect the right of ICCs/IPs to preserve and protect their culture, traditions and institutions. It shall consider these rights in the formulation and application of national plans and policies." (The Indigenous People's Rights Act of 1997. Chapter VI. Section 29.)

¹⁵⁴ "They shall have the right to special measures to control, develop and protect their sciences, technologies and cultural manifestations, including human and other genetic resources, seeds, including derivatives of these resources, traditional medicines and health practices, vital medicinal plants, animals and minerals, indigenous knowledge systems and practices, knowledge of the properties of fauna and flora, oral traditions, literature, designs, and visual and performing arts." (The Indigenous People's Rights Act of 1997. Chapter VI. Section 34.)

¹⁵⁵ "Materials are defined as any biological and genetic organism, either in whole or in part (including progeny, germplasm and microbial cultures), which is collected within the Republic of Philippines, or derivatives, prepared from biological organisms which constitute a partially-purified or fractionated sub-set on an unmodified functional sub-unit, and which are not non-obvious, or are products of nature." (CRA 98. Attachment "4".)

¹⁵⁶ As a member agency of IACBGR, NMP must:

(a) Assist in the review and evaluation of proposals submitted to the IACBGR;

(b) Assist in monitoring and evaluation of the implementation of the Research Agreements as may be requested by other member-agencies concerned;

(c) Act as the official depository of holotypes, properly labeled and preserved, including voucher specimens collected as indicated in the Research Agreement.

¹⁵⁷ Holotype refers to either the sole specimen or element used by the author of scientific name or the one specimen or element designated by such author as the type.

¹⁵⁸ P10,000 is approximately \$227 USD (October 1998 currency exchange rate).

¹⁵⁹ "Net revenue shall be calculated based on the total revenue received by the PC/C-C in connection with any such invention or commercialization, minus all costs, expenses and fees incurred in the discovery and development of the invention, and negotiation of license, royalty, or other commercialization and the acquisition of rights." (CRA 98. Attachment 3. Section 3.3.)

¹⁶⁰ "Quantity refers to the number of pieces collected and the weight of the species. The quantity is approximately 300 pieces a year for three years, with weights ranging between 50-500 grams depending on natural abundance and colony size." (CRA 98. Attachment "1".)

". . . to collect approximately two hundred marine organisms annually from different habitats within the Philippine archipelago . . . this number may be adjusted based on the recollections required . . . Approximately 0.5 kg samples will be obtained from each organism." (CRA 98. Attachment "1A".)

¹⁶¹ Guevarra, Amelia. Assistant Professor, Department of Chemistry, University of Philippines. Telephone interview. 25 March 1999.

¹⁶² The information here presented was compiled from the following sources:

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Chester, C. C. 1996. Controversy over Yellowstone's biological resources. *Environment* 38(8): 10-15.

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Graham, L. 1997. Bio-firms get geyser fever; biotechnology. *Chemistry and Industry* 24: 983.

Scott, Preston. Telephone interview. 29 March 1999.

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Yellowstone National Park/National Park Service and Diversa Corporation. 1998. Cooperative Research and Development Agreement.

¹⁶³ Notable examples are the enzyme Taq polymerase derived from the bacterium *Thermus aquaticus*, discussed further in our paper, and taxol, the anti-cancer compound extracted from the Pacific Yew.

¹⁶⁴ Environmental Law Institute. 1998. *Protecting biodiversity: legal mechanisms concerning access to and compensation for the use of genetic resources in the United States of America*.

¹⁶⁵ The United States signed the CBD in 1993. While Congress has not yet ratified the Convention, Yellowstone Center for Resources Director John Varley and World Foundation for Environment and Development both considered the CBD in forming the agreement between Yellowstone National Park and the Diversa Corporation.

¹⁶⁶ While bioprospecting is not new in the United States, activities on public lands to date have required only a standard collection permit.

¹⁶⁷ United States District Court for the District of Columbia. 1999. Memorandum opinion on Civil Action 98-561.

¹⁶⁸ Graham, L. 1997. Bio-firms get geyser fever; biotechnology. *Chemistry and Industry* 24: 983.

¹⁶⁹ Preston, Scott. Telephone interview. 29 March 1999.

¹⁷⁰ Scott P. T. 1998. Institutional and legal frameworks for benefit-sharing from bioprospecting in U.S. National Parks. Unpublished draft.

¹⁷¹ United States District Court for the District of Columbia. 1999. Memorandum opinion on Civil Action 98-561.

¹⁷² Stanley Burgiel. Facsimile transmission. 1 May 1999.

¹⁷³ 36 CFR§ 2.5 (b) cited in: Environmental Law Institute. 1998. *Protecting biodiversity: legal mechanisms concerning access to and compensation for the use of genetic resources in the United States of America*.

¹⁷⁴ Environmental Law Institute. 1998. *Protecting biodiversity: legal mechanisms concerning access to and compensation for the use of genetic resources in the United States of America*.

¹⁷⁵ Glowka, L. 1998. *A guide to designing legal frameworks to determine access to genetic resources*. Environmental Policy and Law paper No. 34. Gland: IUCN.

¹⁷⁶ Leonard Hirsch. Telephone interview. 29 March 1999.

¹⁷⁷ Scott, Preston. Telephone interview. 29 March 1999.

¹⁷⁸ We might, for the purposes of argument, broaden our definition of stakeholders even further to include all living organisms, who certainly are interested in outcomes associated with biodiversity use and/or conservation. We will, however, limit our discussion to stakeholders with the capacity to articulate their stake, i.e. *Homo sapiens*.

¹⁷⁹ Azevedo, Cristina. Personal interview. 8 March 1999.

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- ¹⁸⁰ Black's Law Dictionary. (1996). West Publishing Company, St. Paul, Minnesota.
- ¹⁸¹ Glowka, L. 1998. *A guide to designing legal frameworks to determine access to genetic resources*. Environmental Policy and Law paper No. 34. Gland: IUCN.
- ¹⁸² Ibid.
- ¹⁸³ Ibid
- ¹⁸⁴ Kloppenburg, J. R. & M. J. Balick, 1996. Property rights and genetic resources: a framework for analysis. In *medicinal resources of the tropical forest: biodiversity and its importance to human health*. M. J. Balick, E. Elisabetsky, & S. A. Laird (eds.), New York: Columbia University Press.
- ¹⁸⁵ It must be noted however, that "non-monetary" benefits can also involve considerable funds from all or some of the parties to the agreement.
- ¹⁸⁶ Cragg, Gordon. Personal communication. 18 March 1999.
- Feinsilver, J. M. & I. H. Chapela. 1996. Commentary: will biodiversity prospecting for pharmaceuticals lead to the discovery of "green gold"? pp. 225–229. In *Biodiversity, biotechnology, and sustainable development in health and agriculture: emerging connections*. Scientific Publication No. 560. Washington DC: Pan-American Health Organization, World Health Organization.
- ¹⁸⁷ Glowka, L. 1998. *A guide to designing legal frameworks to determine access to genetic resources*. Environmental Policy and Law paper No. 34. Gland: IUCN.
- ¹⁸⁸ Susskind, L. 1994. *Environmental diplomacy: negotiating more effective global agreements*. New York: Oxford University Press.
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- ¹⁹⁰ Glowka, L. 1998. *A guide to designing legal frameworks to determine access to genetic resources*. Environmental Policy and Law paper No. 34. Gland: IUCN.
- ¹⁹¹ Ibid.
- ¹⁹² Robinson, J. 1993. The Limits to Caring: Sustainable Living and the Loss of Biodiversity. *Conservation Biology* 7(1): 20–28.
- ¹⁹³ Yield is measured as total production of the biological population minus natural mortality. Ibid.
- ¹⁹⁴ Ibid.
- ¹⁹⁵ "The entire adult population of *Maytenus buchananni*--source of the anti-cancer compound, mantansine—was harvested when a mission sponsored by the US National Cancer Institute collected 27,215 kg in Kenya for testing in its drug development program."
- Reid, W. 1994. Biodiversity prospecting: strategies for sharing benefits. In *Biodiplomacy: Genetic resources and international relations*. Nairobi: African Center for Technology Studies.
- Alyward, B. A. 1996. The pharmaceutical value of species information: opportunities for developing countries. pp. 219–229. In *Medical resources of the tropical forest: biodiversity and its importance to human health*, M. J. Balick, E. Elisabetsky, & S. A. Laird (eds.). New York: Columbia University Press.
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- ¹⁹⁹ Kauffmann-Zeh, A. 1999. Resources lacking to save Amazon biodiversity. *Nature* 398(6726), supplement.
- ²⁰⁰ Schaik, C. P., J. Terborgh, & B. Dugelby. 1997. The silent crisis: the state of rain forest nature preserves. pp. 64–89 In *The Last Stand: Protected Areas and the Defense of Tropical Biodiversity*. R. Kramer, C. P. Schalik, & J. Johnson. (eds.) Oxford University Press.
- ²⁰¹ Grajal, A. 1999. Biodiversity and the nation state: regulating access to genetic resources limits biodiversity research in developing countries. *Conservation Biology*, 13(1): 6–9.
- ²⁰² Vogel, J. H. 1994. *Genes for sale: privatization as a conservation policy*, New York, Oxford University Press.
- Steven R. & S. Fish. 1994. Biodiversity prospecting: using innovative contractual provisions to foster ethnobotanical knowledge, technology and conservation, *Colorado Journal of International Environmental Law and Policy* 5.1: 23–58.
- ²⁰³ Rausser, G. C. & A. Small. 1998. Valuing research leads: bioprospecting and the conservation of genetic resources. Unpublished paper.
- ²⁰⁴ Ibid.

²⁰⁵ Simpson, D. & R. Sedjo. 1996. Investment in biodiversity prospecting and incentives for conservation.

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²⁰⁶ Feinsilver, J. M. & I. H. Chapela. 1996. Commentary: will biodiversity prospecting for pharmaceuticals lead to the discovery of "green gold"? pp. 225-229. In *Biodiversity, biotechnology, and sustainable development in health and agriculture: emerging connections* Scientific Publication No. 560. Washington, DC: Pan American Health Organization, World Health Organization.

²⁰⁷ *The Economist*. 21 February 1999. Shaman loses its magic.