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Regulating access to genetic resources under the Convention on Biological Diversity: an analysis of selected case studies

LILIANA M. DÁVALOS[1,2], ROBIN R. SEARS[1,3], GLEB RAYGORODETSKY[1,4], BENJAMIN L. SIMMONS[5,6,7], HUGH CROSS[1,3], TARAN GRANT[1,2], TONYA BARNES[6,8], LOUIS PUTZEL[6,9] and ANA LUZ PORZECANSKI[1,2,*]

[1]Department of Ecology, Evolution, and Environmental Biology, Columbia University, 1200 Amsterdam Ave., New York, NY 10027, USA; [2]Division of Vertebrate Zoology, American Museum of Natural History, Central Park West at 79th St., New York, NY 10024, USA; [3]The New York Botanical Garden, Bronx, NY 10458, USA; [4]Wildlife Conservation Society, 2300 Southern Boulevard, Bronx, NY 10460, USA; [5]Columbia University Law School, 435 W 116th St., New York, NY 10027, USA; [6]School of International and Public Affairs, Columbia University, 420 W 118th St., New York, NY 10027, USA; [7]Current address: Arnold & Porter, 399 Park Ave., New York, NY 10022, USA; [8]Current address: Division for Sustainable Development, United Nations Department of Economic and Social Affairs, Two United Nations Plaza, DC2-2228, New York, NY 10017, USA; [9]Current address: Search for Common Ground, 1601 Connecticut Ave. NW, Suite 200, Washington, DC 20007, USA; [*]Author for correspondence (e-mail: alporze@amnh.org)

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Abstract. In 1992 parties to the Convention on Biological Diversity (CBD) agreed to develop and implement policies to regulate and facilitate access to genetic resources (AGR). We examine regulations and agreements in Brazil, Colombia, and the Philippines in detail and discuss how these countries are implementing the AGR mandate. In particular, we evaluate progress toward achieving the CBD objectives of conserving biological diversity, using its components in a sustainable manner, and equitably sharing the benefits arising from the use of genetic resources. We highlight the difficulties in developing and implementing these policies, arising from the conflicting goals of regulating and facilitating AGR, as well as the special character of genetic resources, existing *ex situ* collections, issues of ownership and tenure, and the dearth of legal, institutional, and scientific capacity in many countries. We recommend (1) independent, multidisciplinary evaluation of the success of the access policy in achieving CBD objectives, (2) resolution of the conflict between traditional land tenure and legal property rights of genetic resources so as to match conservation obligations with benefit-sharing rights, (3) recognition that benefits obtained from AGR may be entirely non-monetary, and (4) that countries provide a 'two-track' AGR application process separately for commercial and non-commercial users.

Abbreviations: AGR – access to genetic resources, CBD – Convention on Biological Diversity, IACBGR – Inter-Agency Committee on Biological and Genetic Resources, IPR – intellectual property rights, NGO – non-governmental organisation, USA – United States of America.

Introduction

The modern technology to manipulate genetic material belongs in great part to the

multinational corporations and research institutions in the developed world. The raw materials for biotechnology, however, still come from biological sources. Access to the bulk of the world's biodiversity, harboured in large part by developing countries, has traditionally been open (Hardon 1989). As a result, common-pool genetic resources from developing countries have been used freely by researchers, while products derived from genetic resources have become subject to proprietary protection. Thus companies and institutions in developed countries have sometimes accrued great profits from intellectual property rights (IPR) over derivatives of resources obtained from developing countries. Although numerous attempts to restrict transfer of genetic resources across national borders have been made, general regulatory policies have been slow to emerge (Yusuf 1994; Balick and Cox 1996).

The urgency to address issues surrounding proprietorship and access to genetic resources (AGR) has increased in the last two decades, because advances in biotechnology have increased the potential value of genetic resources, while the rate of human-induced biodiversity loss has also increased dramatically. In 1992, in the interests of biodiversity conservation, sustainable economic development, and socio-economic equity, many governments of the world signed the Convention on Biological Diversity. Since its inception, 187 countries have ratified it and started work on its implementation (Convention on Biological Diversity 2002; ten Kate 2002). Among other commitments, CBD signatories agreed, under Article 15, to develop and implement national policies and legislation to regulate and facilitate AGR.

At the core of regulated AGR is the notion that the economic value of natural genetic resources, realised through the development of new uses in biotechnology, would provide economic incentives for the sustainable use of these resources at local, regional, and global levels. This expectation was generated in part by the success of Eli Lilly, a US pharmaceutical firm, in developing a potent anti-cancer drug from the Malagasy rosy periwinkle *Catharantus roseus* (Rajaonarivony 1996), and the rising interest of multinational corporations in bioprospecting. Developing nations viewed the CBD as a means to control the transfer of their genetic resources, thereby improving their position in the global political arena and obtaining capital for development and conservation (Kothari 1997; Glowka et al. 1998).

To achieve the goals of the CBD related to regulated AGR, policy makers must overcome several primary obstacles. First, they must take into account the special character of genetic resources. 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 the existing *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 various stakeholders, including national and state governments, local populations, private industry, and non-governmental organizations (NGOs), on behalf of humankind have all claimed rights to genetic resources. Finally, a dearth of legal, institutional, and scientific capacity in many countries seriously hampers efforts to facilitate and regulate AGR.

Progress in regulating AGR varies substantially from nation to nation. Only a few countries, such as the Philippines, Costa Rica, and Andean Pact signatories, have enacted regulations in response to the CBD mandate. Many other states formulated draft legislation that is now in the process of enactment, subject to intense review and lobbying by stakeholders whose interests in many cases are yet to be reconciled. In this paper we study the regulatory responses undertaken by Colombia, Brazil, and the Philippines in developing AGR legislation. In analysing these cases we highlight the difficulties in developing and implementing these policies, and recommend ways to overcome them.

Methods

In addition to the cases presented here, we examined cases of regulated AGR from Fiji, Cameroon, Costa Rica, and the United States of America (USA). These cases represented different regions of the world and a variety of stakeholders, including private actors, NGOs, research institutions and governments, as well as a broad array of regulatory environments (EPS Workshop 1999). Conclusions and recommendations presented here draw from all these cases, although we present details of only three. We analyse an agreement in Brazil, a nation developing AGR legislation at both federal and state levels. We also examine two cases in countries that have adopted legislation specifically designed to comply with the mandate of Article 15: Colombia, a country subscribed to a legally binding regional agreement governing AGR; and the Philippines, which has developed comprehensive legislation to this end.

The data we collected for all cases include descriptions of how benefit sharing, prior informed consent, local knowledge, sustainable use, and conservation have been addressed. These formed the general framework where we analysed the specific elements common to successful genetic resource access agreements and legislation (EPS Workshop 1999). In this paper we examine how the implementation of Article 15 has achieved the CBD objective of regulating and facilitating AGR, and briefly discuss the complementary CBD objectives of conserving biodiversity and establishing sustainable use of its components. Therefore, we focus our analysis on AGR cases after CBD ratification:

1. The BioAndes attempt to bioprospect in Colombia under Decision 391 of the Andean Pact,
2. The National Cancer Institute – *Universidade Paulista* agreement and proposed legislation in Brazil, and
3. Access agreements and legislation in the Philippines.

Case studies

An application of Andean Pact Decision 391 in Colombia

Andean Pact countries – Bolivia, Colombia, Ecuador, Peru, and Venezuela – may

jointly harbour the largest proportion of the world's biological diversity, and some still possess a large proportion of their original forest cover. 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 (McNeely et al. 1990; Bryant et al. 1997). The perceived need to increase control over these vast genetic resources led to the formulation of Decision 391, a common regime on AGR in Andean Pact countries (Comisión del Acuerdo de Cartagena 1996).

The first attempt at applying the Andean Pact Regime as a commercial AGR agreement in Colombia was initiated by BioAndes – a private joint venture between Andes Pharmaceuticals, Inc. (Washington, DC) and ERS Asociados (Bogotá) – and was mediated by the Colombian Ministry of the Environment. Andes Pharmaceuticals, Inc. was founded in 1993 in response to the signing of the CBD. ERS Asociados is a private investment company dedicated to attracting foreign expertise. BioAndes was founded as an equitable (50/50) partnership between the two companies in 1994 (Asebey 1996; E. Asebey, personal communication).

The application and decision-making processes in this case of AGR were extremely involved and complicated. There were two official requests from BioAndes for AGR, two rejections from the Ministry and two pleas in the intervening and final attempts to receive permission from the Ministry. This process lasted 3 years and involved several NGOs, two scientific institutions as advisers to the Ministry, and two teams of lawyers. BioAndes claims to have spent US $ 1 000 000 (E. Asebey, personal communication) in its failed attempts to gain access to Colombia's genetic resources. All of the Ministry's resolutions rejecting BioAndes's requests and pleas were grounded partially on Decision 391 of the Andean Pact (Comisión del Acuerdo de Cartagena 1996).

Decision 391 of the Andean Pact provided the framework for the Ministry's evaluation and ultimate decision. Among other goals, Decision 391 aims to ensure fair participation and equitable sharing of benefits derived from AGR in all Andean Pact countries. It also provides 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, however, leaves the specific standards for benefit sharing, technology transfer, capacity building, and traditional knowledge open to case-by-case negotiation (Flórez and Pimiento Chamorro 1998). Since many of the Ministry's reasons for rejecting the BioAndes proposal before the negotiation phase allude to such specifications, Decision 391 was used in a highly interpretative manner to reject the requests.

The Ministry followed the proprietary rights and the overall application process prescribed by the Decision, but the specific reasons invoked by the Ministry in its Resolutions are not clearly linked to Decision 391. No specifications of cash benefits – up-front payments, royalties, or access fees – were solicited by the Ministry in more than 30 information requests to BioAndes between February and November 1997. Nevertheless, the distribution of (monetary) benefits section of the first request was interpreted by the Ministry as ''not pursuant of these [Constitutional, CBD, Decision 391] principles, given that fair and equitable sharing of benefits for

the State derived from access is not set forth''. The Ministry's emphasis on monetary benefits was spurious, because Decision 391 does not require that applications stipulate monetary benefits at all.

Decision 391 also requires of applicants to name a ''national support person or institution''. Given that the application process should be equally required of all users, this requirement 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 the application process remain open. The encumbering effects Decision 391 has had on biodiversity research in Latin America have already been sharply noted by Grajal (1999a, b). The exchange between Ministry and BioAndes reported here highlights the difficulties in reconciling the dual objectives of regulating AGR while facilitating the development of AGR agreements. In this respect, Decision 391 represents a necessary but not sufficient step in balancing the two goals for both commercial and research purposes.

Bioprospecting in Brazil under a Developing Regulatory Environment

Following Brazil's ratification of the CBD in 1994, national concern mounted around formalising the principles of the Convention through legislation. Particular attention was focussed on Article 15 on controlling AGR and obtaining benefits therefrom. The government of Brazil has responded thus far with the development of three federal bills, for debate in the National Congress (C. Amaral de Azevedo, personal communication). To date, only two states in the federation, Amapá and Acre, have passed AGR legislation and a third, São Paulo, is actively developing such regulations. The debates revolve around three main issues: protection of indigenous knowledge, scope of legislation (detailed vs. generic), and specifications for benefit sharing.

Prior to this process, access to biological organisms, derived products, and associated traditional knowledge was unregulated for Brazilian nationals. Data and material collection by foreign researchers was regulated through National Decree 98.830 signed in 1990, which dictates, *inter alia*, that foreign scientists may only conduct research in co-ordination with a Brazilian institution. While provisions are made in the decree for assuring international collaboration and sharing of intellectual results of the research, there are two obvious limitations: the absence of protection for indigenous or traditional knowledge, and lack of benefit-sharing provisions.

At the federal level, in 1995 Senator Marina Silva introduced the first of the proposed bills, Bill no. 306/95. The second, an attempt to move the Silva proposal through Congress, was introduced by Deputy Jaques Wagner in 1998 (no. 4579/98) and differs only in affording stronger rights to indigenous peoples and traditional communities. Both these proposals were developed with public input. A government office developed the third bill, submitted in 1998. The distinguishing feature of this bill is its generic nature that leaves the details of regulation to be developed and implemented via regulatory mechanisms yet to be established (C. Amaral de Azevedo, personal communication).

At the state level, São Paulo is working to develop legislation covering AGR. The state Environmental Secretary issued Resolution 001-99 in January 1999, aiming to establish more control over the nature and procedures of research and bio-prospecting endeavours until specific legislation, either state or federal, is enacted. Among other things, this resolution mandates the elaboration of a state law. A bill has been drafted by the São Paulo State Biodiversity Programme for public discussion (São Paulo State Government Environmental Secretariat s.d.). Other states have already passed legislation: the state laws of Amapá (Law no. 388/97 and Decree no. 1624) and Acre (State Law no. 1235/97) were modelled after the federal Silva bill, but have been criticised for being passed hastily and for including cumbersome requirements (RRS, personal observation).

Despite the lack of solid regulations, access requests continue and working agreements have been reached. In the agreement we examined, the National Cancer Institute of the USA has taken an innovative approach to collaboration by developing a Memorandum of Understanding with the Brazilian Government (ten Kate and Wells 1998). The National Cancer Institute has sought to conduct chemical analyses of botanical materials from a conservation unit in the State of São Paulo, Brazil. The National Cancer Institute is collaborating with the *Universidade Paulista*, a private educational institution in São Paulo that will collect the biological material and conduct biochemical extraction and screening for biological activity. *Universidade Paulista* will benefit from the technology and materials transfer, and eventual sharing of royalties.

The first contract between the two institutions was signed in 1997. The extensive benefit-sharing provisions present in the Memorandum of Understanding, including recognition of IPR and technology transfer, may improve opportunities for sustainable long-term exploitation of the genetic resources. The outcome of the collaboration depends on the *Universidade*'s success in gaining permission from state and federal authorities to collect biological material, which in turn depends on the development of the legislation. Under the terms of the Environmental Secretary contract, until federal legislation is passed neither patents nor authorisation to commercialise any product derived from biological resources collected will be possible. Despite this confusing legislative period, the Memorandum of Understanding has proceeded because it is remarkably flexible. Since it establishes extensive technology transfer and training in the initial stages, many provisions of the agreement can be carried out before access to the resources is granted.

It is apparent from this case that the period when a country is developing legislation is the most difficult time for stakeholders to obtain access. Once the legislation has been passed this situation may improve, as guidelines for requesting access, regulatory competence among agencies, and the property rights of the resources become clearer (K. Moran, personal communication). When Resolution 001-99 was adopted, the Environmental Secretary of São Paulo required ongoing field projects to negotiate mutually agreed terms within a short period. New access applications in São Paulo were placed on hold.

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 be passed into law if it contains too many specific regulatory premises and directives,

and, if so, what should its scope be? Second, what will be the interaction between state and federal law? Will applicants be required to file with both state and federal agencies? 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 honoured by state agencies?

Bioprospecting under Presidential Executive Order 247 in the Philippines

In 1995, in response to a non-governmental initiative aimed at implementing the CBD, the Philippine government issued Presidential Executive Order 247 (Presidential Office of the Philippines 1995), which established a legal framework for regulating the prospecting of biological and genetic resources. The Executive Order represented one of the first attempts by a nation to formally regulate access to biological diversity and incorporate provisions for benefit-sharing.

In June 1996, the Philippine Department of Environment and Natural Resources issued Department Administrative Order No. 20, setting forth the rules and regulations governing the implementation of the executive order, and providing details about the application and review process for agreements between parties seeking AGR.

The Executive Order established the Inter-Agency Committee on Biological and Genetic Resources (IACBGR) to review applications for AGR. IACBGR members include not only representatives from various government agencies, but also a representative from an NGO and a member of a 'people's organisation' representing the interests of indigenous communities.

The executive order distinguishes between academic research agreements, entered into between universities, academic institutions, governmental agencies, and inter-governmental agencies for the purpose of academic and scientific research, and commercial research agreements entered into between private parties, corporations, or foreign international entities for commercial purposes. According to the executive order, the requirements for a commercial research agreement are much narrower and more specific than the requirements for an academic research agreement. This can be seen as an implicit recognition by the Philippine government that parties interested in accessing genetic materials for commercial purposes often have different goals than those accessing material for academic purposes, and therefore, should be subject to different requirements. It should also be noted that where appropriate, a commercial research agreement or academic research agreement must also comply with other Philippine state regulations, such as the Indigenous People's Rights Act of 1997 and the National Integrated Protected Areas System Act of 1992 (Presidential Office of the Philippines 1992, 1997).

The first application approved by the Philippine government pursuant to the executive order was a commercial research agreement between the Marine Science Institute of the University of the Philippines, the Department of Agriculture of the Philippines, and the University of Utah, USA. The original terms and conditions of the proposed agreement were reviewed in January 1998 at the 10th meeting of the IACBGR. In June 1998, at the 11th meeting of the IACBGR, the agreement was

approved. The second application approved was an academic research agreement between the University of the Philippines and the Philippine government. The academic agreement was provisionally approved in 1999 by the IACBGR.

The commercial agreement, 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'' (Department of Agriculture, University of Utah, and Marine Science Institute of the University of the Philippines 1998).

The academic agreement between the University of the Philippines and the government was the first of its kind developed and is designed to be a model for subsequent academic agreements (Dr A. Guevara, personal communication). The multiparty agreement represented a culmination of over 2 years of preparatory work. According to the executive order and the administrative order, if the academic activities result in identifying certain genetic resources that have commercial potential, then a commercial agreement must be developed.

The two agreements noted above have attempted to mitigate the major obstacles that stand in the way of successful implementation of conservation, sustainable use, and equitable benefit sharing – the main objectives of the CBD. The special nature of genetic resources was addressed in the agreements by including specific provisions about their geographic scope, IPR, and unlimited access to *ex situ* collections of the materials. Specific provisions about ownership of the materials, material transfer agreements, and patenting of the inventions addressed ownership and tenure of genetic resources. Technology transfer and training of local staff were included to deal with the inadequacy of local institutional capacity. Finally, different stakeholders, from local communities to Protected Areas Management Board were defined and the mechanisms for ensuring their consent were outlined.

Because of the recent nature of these two agreements, it is difficult to ascertain how effective they will be in achieving the CBD's objectives. All that is certain at the present time, is that the executive order and the administrative order create a comprehensive regulatory structure that ensures that the goals of CBD are, at the very least, contemplated in agreements between parties seeking AGR.

Discussion

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 requesting access, but only if the regulations are not prohibitively restrictive. Extreme regulation raises the overall cost of access to biological material and may thus prevent genetic resources from being used legally. This problem affects national, international, commercial, and non-commercial ventures alike.

It is imperative for the success of the CBD that policy makers reconcile the

potentially conflicting goals of regulating and facilitating AGR. New AGR regulations may further increase the cost of negotiating access by nullifying pre-existing agreements or requiring re-negotiation of terms. Consequently, the process of developing regulations creates a 'window of uncertainty' during which source country authorities are inclined to reject or postpone access decisions. Based on the cases we examined, the balance between regulating and facilitating access has favoured regulation over facilitation. The complexity of the issue is illustrated by the failed BioAndes applications to gain access in Colombia, and subsequent reports of regulatory obstacles to research in Colombia (LMD, personal observation), Venezuela (J. Ochoa, personal communication), and all Andean Pact countries (Grajal 1999a). In the Philippines only a handful of applications have been approved, but it must be noted that these successful cases will most likely serve as templates for future applications, thereby improving the chance of future approval of requests.

Except for the case of the Philippines, in which an executive order expedited the process, the long process of policy implementation has created impediments to collection of genetic resources. As seen in the cases of Colombia and Brazil, the period during which a country is developing legislation, or interpreting international agreements, is the hardest for interested parties, both national and international, to obtain access.

A key element missing from the access legislation cases reviewed is an evaluation step of the compliance of access agreements with the goals of the CBD. Have the benefits derived had any discernible impact on the area from which resources are obtained? Have any major unintended social or environmental impacts resulted from the new regime? Has regulation facilitated access? Provisions for broad evaluation of this kind are not established in any of the seven regulatory measures examined (see Methods).

If bioprospecting is to become a viable means of achieving biodiversity conservation, socio-economic sustainability is as important as ecological sustainability (Rausser and Small 2000). The socio-economic sustainability criterion is defined as the capacity to meet the economic needs and aspirations of the human users over an extended period of time (Robinson 1993). We can only indirectly infer socio-economic sustainability from the cases, but success in this respect will largely depend on whether the regulatory regime provides incentives for sustainable use, what benefits are derived from access, who receives the benefits, and who has responsibility for the stewardship of the resources.

A common theme in AGR discussion is that cash profits generated from bioprospecting would enhance conservation. Nonetheless, at the time of this analysis, no royalty or commercialisation-derived monetary benefits have resulted from any of the agreements. If the past decade of bioprospecting is indicative of potential outcomes, then in the large majority of cases the benefits that can be expected from bioprospecting will remain primarily non-monetary, i.e., capacity building, technology transfer, joint research, and training.

The access agreements we reviewed emphasise the training and capacity-building responsibilities of the foreign parties. Thus, source countries collect the significant

non-monetary benefits that prospectors agree to exchange for access from the beginning of a project. Therefore, training and capacity building are likely to be much more important to source countries than monetary benefits in the short and long term. These benefits may also address conservation goals in a shorter term.

In the three cases reviewed benefits will accrue mostly to the state, and less to the local stewards of the resource. In the Brazilian senate bills, for example, the power to direct the distribution of the benefits lies with the competent authority, which will most likely be a government agency. Moreover, agreements for AGR may create few incentives for conservation by local communities, whose members are primary users and stewards of the land but do not legally own the property.

Governments have asserted their sovereign rights over genetic resources, but the land remains under traditional tenure. Typically, only resource owners participate in the negotiation of agreements, with the resource owners as primary beneficiaries. However, in many cases the resource owners are not the primary users and stewards of the land. In these cases, the burden of sustainable use and conservation rests with the stewards of the land. It is unlikely that these stewards will embrace sustainable land-use practices if AGR policy does not provide them with benefits derived from the genetic resources they tend.

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 high monetary stakes, access regulations have become increasingly restrictive and commerce-oriented. Hence a cumbersome, unnecessarily strict application process is imposed on 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 recognise the fundamental differences between commercial and non-commercial research in AGR policy may cause essential research to grind to a halt.

From our analysis, a number of recommendations pertinent to policy and decision making in regulating AGR emerged. They highlight issues that need to be addressed in development and implementation of AGR legislation and agreements if countries are to achieve the objectives identified in the CBD.

Recommendations

Independent, multidisciplinary evaluation of the success of the access policy in achieving CBD objectives should be incorporated into AGR regimes. It is essential 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, which must be periodically renewed, the renewal process could require an evaluation report.

National policy should address the conflict between traditional land tenure and legal property rights of genetic resources, so that resource stewards have conservation obligations that match the benefit-sharing rights implicit in AGR policy.

When establishing agreements, all parties should acknowledge that benefits

obtained from access may, for the most part, be non-monetary, and that monetary benefits may take a long time to accrue, if at all.

Since there is no objective criterion to draw 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. Therein any access applicant would be able to choose between either one according to their priorities.

Type I agreement: a simple research permit in which researchers forgo the right to any future monetary benefits arising from commercialisation and IPR, which belong to the resource owners. In this case, the researcher who discovers an economic value in a biological sample should agree to inform the owners so that they can protect their property rights.

Type II agreement: a more complex contractual agreement which would involve negotiations of IPR 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 for government agencies 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 waiving, in a legally binding agreement, any ownership rights over future commercial discoveries and resulting benefits, parties interested only in basic research would avoid more costly negotiations. The Type I agreement represents one of the most restrictive arrangements possible, where users are only granted ownership to the sample itself and permission to study only the material they collect.

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 commercialisation of any discoveries by the resource owners, nor would it prevent users from entering into a more complex Type II agreement in the future.

Type II agreements could be structured as a framework 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. By preventing over-regulation, a Type I agreement would encourage the basic biological research that is indispensable to achieve the goals of the CBD.

Conclusions

Do the agreements we examined provide ways to overcome the obstacles to regulating access and biodiversity conservation? As can be expected, the degree to which they accomplish this goal varies among the examined cases and the types of obstacles. Some of the obstacles outlined here seem to be insurmountable, while

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

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

As illustrated by the differences between the alternative federal bills in Brazil, reconciling the diverging interests of stakeholders remains a challenge in many instances. But in other cases, such as the Philippines, the involvement of a variety of stakeholders seems to have been accomplished. As noted in the Brazilian and Philippine case studies, the obstacles arising out of low institutional, legal, and scientific capacity are those most rapidly addressed in AGR agreements and regulations.

Since completion of our original research in 1999, progress toward the facilitation of access agreements has been slow in Brazil, Colombia, and the Philippines. Substantial legal changes have been implemented in Brazil, where federal provisional measure No. 2.186-16, 8/2001 (Presidência da República 2001) created a national body that now evaluates and regulates access requests, even discriminating between commercial and non-commercial requests. Although no request for access has been granted yet (L. Coradin, personal communication), the 'window of uncertainty' that has hindered access in Brazil for the last several years could be closing. Decision 391 has allowed for research agreements in Bolivia and Venezuela, but not in Colombia, where BioAndes was rejected twice, two applications were dropped, and two are pending (A.M. Hernández, personal communication). In the Philippines, the executive order has not been as successful in facilitating access as initially hoped, given that only a few of the more than thirty recent applications have been approved (Peria 2002). Because of the complexities that lie at the intersection of research, policy, and benefit-sharing, what should be an instrument of local empowerment and conservation financing can become a major obstacle to much needed biodiversity research. Unless this problem is recognised and corrected by those formulating, enacting, and enforcing regulation, Article 15 will be credited only with delaying our efforts to understand biodiversity as it vanishes.

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